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14. ABSTRACT

The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer offered in two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private). Specific aims: controlling for stage at diagnosis and co-morbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with and without prostate cancer between non-VA and VA hospitals. During the first year of this prospective cohort study, we have established successful recruitment and retention program. After finalizing the research protocol, we have recruited 330 younger (< 65 Years) patients from the Urology and Radiation Oncology clinics, University of Pennsylvania Health System and VA medical center with a retention rate of more than 84% for our follow-up surveys. Based on the preliminary results, we have published three manuscripts and one is under review.

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Quality of Life, Cost of Care and Satisfaction with care

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INTRODUCTION

Proposed Abstract:

Background: Cost and health-related quality of care are particularly relevant to prostate cancer because of multiple treatment options with varying outcomes. Due to uncertainty in the screening and treatment, debate on outcomes such as quality of life, satisfaction with care and cost of care continues. Our recent research indicated that type of treatment received for a given stage of prostate cancer varied by ethnicity and age. Men with early stage prostate cancer often live long after diagnosis and treatment and desire to maximize their quality of life. The outcome of this study will facilitate clinical and policy decision making for effective and equitable care.
Objectives/Hypothesis: The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer offered in two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private).
Specific aims: controlling for stage at diagnosis and co-morbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with and without prostate cancer between non-VA and VA hospitals.
Study Design: This study uses a prospective cohort design to assess and compare across Caucasians and African Americans, health related quality of life (HRQoL) and cost of care for prostate cancer patients, younger than 65 years. A total of 300 participants will be recruited from the urology services at the Hospital of the University of Pennsylvania (HUP) and Philadelphia VA Medical Center. Data will be collected on patient age, ethnicity, education, date of prostate cancer diagnosis and treatment, health insurance, diagnostic and therapeutic procedures, inpatient hospitalizations, PSA, PSADT, Gleason score, cancer stage (TNM), physician and ambulatory clinic visits, laboratory and x-ray, and pharmaceuticals. To assess HRQoL, all participants will receive the Prostate Cancer Index, SF-36, family out of pocket-indirect cost survey and CSQ-8 via mail and a follow up phone call. Baseline data will be collected within 1-2 weeks after diagnosis of prostate, and after recruitment for the control group. Subsequent follow up will be done at three months' interval up to two years. We will compare mean direct medical and incremental cost of care for all conditions and HRQoL across two ethnic groups, controlling for stage and Charlson co-morbidity score. HUP costs for the same services will be applied to VA patients. Cost-effectiveness of prostate cancer treatment will be compared across ethnic groups. We will obtain data on primary sources of treatment and costs from hospital medical records, chart review, and hospital based administrative database (Pennsylvania Integrated Clinical and Research Database system). Descriptive and inferential statistical (t-test, chi-square, and odds ratio) analysis will be performed. PSA doubling time will be computed and compared across ethnic groups. Logistic and pooled regression models will be used. The dependent variables of two separate regression models are total cost and quality of life. The independent variables are age, treatment type, health insurance, Charlson co-morbidity score, PSA level and Gleason score. The regressions will be repeated for both ethnic groups and parameters of estimates will be compared. Stratified analysis will be performed based on ethnicity, stage at diagnosis and treatment type. Factors associated with progression of cancer will be analyzed and compared across groups. Finally, Markov models will be used to analyze and compare cost-effectiveness and progression of prostate cancer treatments across two ethnic groups and comparison will be made between VA (public) and non-VA (private) hospitals.

BODY

After completing the final research protocol, the process of recruiting newly diagnosed prostate cancer patients for this grant was initiated in February of 2004. We have recruited 330 younger men with prostate cancer as of January 2006. The specific steps of this process are: (1) contacting the patients; (2) explaining the study; and (3) obtaining the consent.

Task 1. Recruitment of Patients (completed)

a. Design of final protocol – Completed task

b. Potential patients were contacted at the urology and radiation oncology clinics after introduction by their urologist and radiation oncologist. Newly diagnosed patients were also contacted at their pre-prostatectomy classes, organized by the urology clinic. The newly diagnosed prostate cancer patients were contacted at the Veteran Affairs Medical Center during their urology clinic visit.
Research assistant held a detailed discussion with the patients regarding the study.

c. Consent was obtained from interested patients

d. Recruitment of patients

e. Appropriate medical record abstract form has been developed to extract information from individual medical record

f. A unique patient identifier was assigned to each patient. This information is maintained as highly confidential at all times.

Table 1 shows the total number of patients recruited during the period between 2/1/2004 to 1/31/2006. Some of the newly diagnosed prostate cancer patients were at the urology clinics for a second opinion only, and were not eligible for our study. So far, we have obtained baseline data on a total of 330 newly diagnosed younger (< 65 years) prostate cancer patients from the University of Pennsylvania Hospital (n= 240) and from the Philadelphia VA Medical Center (n=90).

Table 1: Recruitment of Newly Diagnosed Prostate Cancer Patients (< 65 Years)

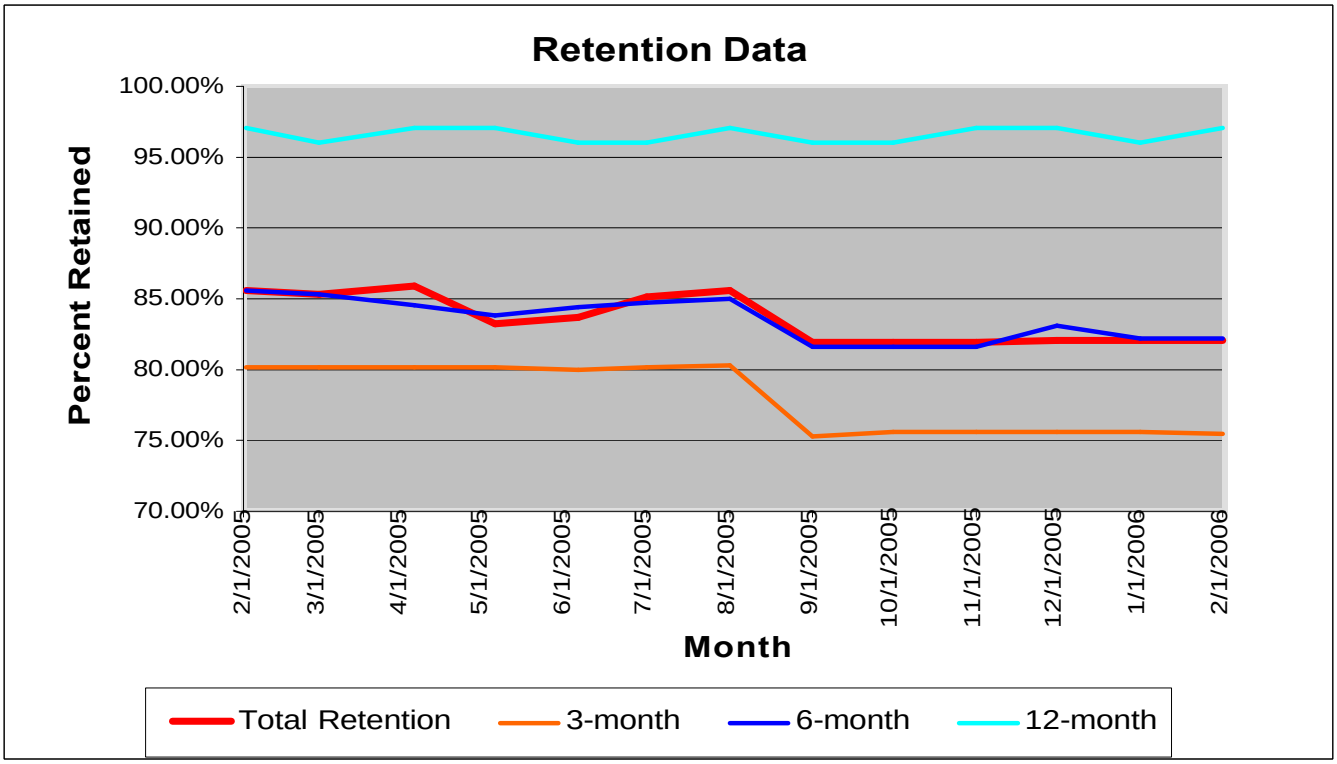
	Hospital of the University of Pennsylvania		Philadelphia VA Medical Center		Total	
	Number of eligible patients	Number recruited	Number of eligible patients	Number recruited	Number of eligible patients	Number recruited
TOTAL	600	240	300	90	900	330

Task 2: Baseline Data Collection (continued)

We have completed baseline data collection for all the 330 patients recruited from the UPHS and PVAMC. We have recruited newly diagnosed prostate cancer patients from the urology and radiation oncology clinics at the University of Pennsylvania Health System (UPHS). We also recruited patients from the Philadelphia VA Medical Center. After obtaining a written consent from the patient, we collected the patient's baseline demographics and quality of life data using the UCLA prostate cancer index, FACT-P, QWB-SA and SF-36. The subsequent follow-ups are done at 3, 6 12 and 24 months beyond a patient's entry into the study. Data on following variables was obtained: Age, ethnicity, types of insurance, living arrangement, marital status and mortality. All the baseline data has been entered and data cleaning is ongoing. A medical record abstraction form was developed to extract clinical data such as PSA scores, Gleason scores, stage of cancer at the time of diagnosis, type of treat received and diagnostic procedures performed from individual medical records.

Patient Follow-up and Retention

Figure below shows the monthly retention activity for our follow-up surveys.



Task 3: Administration of Patient Satisfaction Questionnaire - continued

The patient satisfaction care (CSQ8) survey was administered at baseline and at each subsequent follow-up. All patient data satisfaction data has been ongoing. Preliminary data are presented in Tables 19 and 20.

Task 4: Develop Plan for Follow-up Patient interview-completed

a. A tracking system was developed to track the patient recruitment and contact process. During the follow-up period, seven patients died, (non-prostate cancer related cause), four were from the UPHS and three were from the VA. We provide each patient with $10 in compensation at the time of recruitment into the study and $5 at each successful follow-up. This has helped in generating good response rates.

Task 5: Follow up interview and Health Related Quality of Life, and Cost (resource Utilization) Data Collection - continued

a. Surveys are sent out at each follow-up time period to collect data from enrolled patients.

b. Non-respondents are contacted over the telephone and are offered the option to complete the survey over the telephone.

c. Data collection and data entry is being done simultaneously.

d. Date of diagnosis, date of treatment & length of stay, other relevant medical diagnoses and medications data are being obtained from medical charts.

e. Health Related Quality of Life data is collected using SF-36, QWB-SA, FACT-p and UCLA Prostate Cancer Index.

For those patients who have completed 12 months into the study, we have completed medical chart review to obtain following clinical data via medical chart review: date of diagnosis, date of treatment & length of stay; type of treatment/procedures; hospital charges & reimbursements, number and type of medications; number of other procedures, principal DRG diagnostic studies and relevant medications. The results are presented in Tables 15-18. Overall satisfaction with care at 3, 6 and 12 months follow-up is presented in Table 19. A comparison of satisfaction with care at 3, 6 and 12 months follow-up by ethnicity is presented in Table 20.

Table 2: Demographics of the study group (age < 65, n=330)

Variable		Percent
Race	Caucasian	58.18
	African American	41.82
Education	8 grades or less	0.34
	Some high school	4.46
	High school graduate	25.09
	Some college	26.12
	College graduate	17.53
	Advanced or graduate training	26.46
Marital status	Married	72.57
	Single	12.15
	Widowed	2.78
	Divorced	12.50
Current employment status	Working full-time	55.44
	Working part-time	3.86
	Retired	26.66
	Other	14.04
Household income	Under $10,000	6.74
	$10,001 up to $20,000	9.22
	$20,001 up to $30,000	10.64
	$30,001 up to $40,000	6.38
	$40,001 up to $50,000	5.32
	$50,001 up to $70,000	13.83
	$75,001 or more	46.10
		1.77

The demographic characteristics of the study group are presented in Table 2. The mean age was 57.2 (standard deviation= 4.5). Comparison of demographic characteristics by hospital is shown in Table 3.

Table 3: Comparison of demographics across VA and UPHS groups at the baseline (age<65)

Variable		VA (n= 90)	UPHS (n=240)	
Race (%)	White	25.60	70.40	? = 62.62
	African American	74.40	29.60	p=<.0001
Education (%)	8 grades or less	0.00	0.49	? = 39.14
	Some high school	7.05	3.40	p=<.0001
	High school graduate	30.59	22.82	
	Some college	44.71	18.44	
	College graduate	9.41	20.87	
	Advanced/graduate training	8.24	33.98	
Marital status (%)	Married	43.90	83.97	? = 50.10
	Single	28.05	5.83	
	Widowed	3.66	2.43	p=<.0001
	Divorced	24.39	7.77	
Current employment status (%)				? = 70.17
Working full-time		17.50	70.24	p=<.0001
Working part-time		7.50	2.44	
Retired		42.50	20.49	
Other		32.50	6.83	
Household income (%)				? = 138.23
Under $10,000		21.25	0.99	p=<.0001
$10,001 up to $20,000		27.50	1.98	
$20,001 up to $30,000		20.00	6.93	
$30,001 up to $40,000		10.00	4.95	
$40,001 up to $50,000		5.00	5.45	
$50,001 up to $70,000		5.00	17.33	
$75,001 or more		6.25	61.87	

Table 4 shows the baseline general health status and HRQoL (UCLA-PCI) of all newly diagnosed, elderly prostate cancer patients (UPHS and VA combined). All raw scores were converted to a scale of 0 to 100. A score of zero indicates extremely limited function/activity, whereas, a score of 100 indicates excellent function/activity. Physical functioning is a measure of activities during a typical day. Lower score on physical functioning is indicative of more limited the movements. Social functioning is a measure of how physical health interferes with social activities with family, friends, neighbors or groups. As mentioned earlier, the score varies from 0 (high problem) to 100 (no problem). Bodily pain indicates presence of bodily pain and its impact on normal work and the score ranges from 0 to 100. A score of 100 indicates no pain and a score of 0 indicates extreme or very sever pain. Vitality measures level of energy, higher score meaning better vitality. Mental health is a measure of emotional well-being. The score on mental health ranges from 0 to 100. Higher score suggests better mental health. Urinary function is a measure of urinary habits. The score varies from 0 to 100. Higher the score, better the urinary function. Bowel function indicates bowel habits and abdominal pain. Higher score on bowel function indicates better bowel function. Sexual function is a measure of sexual function and sexual satisfaction. The score ranges from 0 to 100, higher score indicating better sexual functions. Similar baseline data for comparison between UPHS and VA groups is presented in Table 5. The demographic comparison by ethnicity is presented in Table 6. Mean age and mean Charlson comorbidity scores were comparable between African American participants and Caucasian participants (57.7 (4.5) vs. 56.8 (4.96), p=.1179; 2.16 (2.4) vs. 1.6 (2.6), p=.3). The mean overall quality of well being, as measured by the Quality of Well-being (or QWB) survey was comparable between baseline and 12 month follow-up (0.019 (std=0.15) vs. 0.6966 (std=0.5)). At baseline, mean quality of well being was comparable between UPHS and VA hospital (0.7252 (std=.13) vs. 0.6729 (std=.19); p=0.1055). Comparable results were obtained for comparison across

African Americansand Caucasians (0.6991 (std=.17) vs. 0.7044 (std=.15); p=0.8715). At 12 months, the mean quality of well being across UPHS and VA was different (0.7230 (std=.15) vs. 0.6252 (std=.17); p=0.0294). However no significant change was observed between African Americans and Caucasian at 12 month (0.7010 (std=0.04) vs. 0.6948 (std=0.02); p=0.8912).

Table 4: Overall General Health and Prostate Cancer Index at the baseline (age< 65, n=330)

Variable	Mean (standard deviation)
General Health	
Physical functioning	65.30 (20.65)
Role-physical	76.83 (37.96)
Emotional function	73.43 (39.70)
Vitality	65.15 (22.70)
Mental health	73.96 (19.43)
Social function	80.05 (25.10)
Bodily pain	81.96 (25.77)
General health	68.23 (23.65)
UCLA Prostate Cancer Index	
Urinary function	89.62 (19.14)
Bowel function	87.77 (13.91)
Sexual function	60.17 (27.86)
Urinary bother	85.12 (23.89)
Bowel bother	89.52 (20.11)
Sexual bother	64.89 (37.96)

Table 5: Comparison of general health and HRQoL of VA and UPHS groups at baseline (age<65 yrs)

Variable	VA (n=90)	UPHS (n=240)	p value
General Health			
Physical functioning	51.16 (24.33)	72.29 (14.08)	<.0001
Role-physical	55.79 (45.03)	87.24 (28.83)	<.0001
Emotional function	63.51 (44.32)	78.36 (36.31)	.0029
Vitality	55.53 (23.42)	69.95 (20.78)	<.0001
Mental health	68.28 (20.40)	76.80 (18.33)	.0004
Social function	68.49 (29.41)	85.86 (20.35)	<.0001
Bodily pain	67.55 (30.68)	89.17 (19.31)	<.0001
General health	55.77 (24.06)	74.56 (20.80)	<.0001
UCLA Prostate Cancer Index			
Urinary function	86.90 (18.78)	91.00 (19.23)	.0860
Bowel function	82.75 (15.42)	90.37 (12.31)	<.0001
Sexual function	50.38 (29.40)	65.19 (25.70)	<.0001
Urinary bother	79.12 (26.68)	88.24 (21.73)	.0022
Bowel bother	83.07 (25.26)	92.82 (15.99)	<.0001
Sexual bother	55.21 (39.72)	69.89 (36.12)	.0020

Table 6: Comparison of demographics across ethnicity at the baseline (age<65 yrs)

Variable	Caucasian (n=192)	AA (n=138)	
Hospital type			? =62.8
UPHS	88.0	51.4	p=<.0001
VA	12.0	48.6	
Education (%)			? = 36.00
8 grades or less	0.52	0.00	p=<.0001
Some high school	2.60	8.08	
High school graduate	21.88	31.32	
Some college	19.79	38.38	
College graduate	19.27	14.14	
Advanced or graduate training	35.94	8.08	
Marital status (%)			? = 8.94
Married	77.89	62.24	p=.0301
Single	10.00	16.33	
Widowed	1.58	5.10	
Divorced	10.53	16.33	
Current employment status (%)			? = 43.51
Working full-time	68.26	30.21	p=<.0001
Working part -time	3.70	4.16	
Retired	21.16	37.50	
Other	6.88	28.13	
Household income (%)			? = 68.30
Under $10,000	3.74	12.63	p=<.0001
$10,001 up to $20,000	4.81	17.89	
$20,001 up to $30,000	5.88	20.00	
$30,001 up to $40,000	4.81	9.47	
$40,001 up to $50,000	3.21	11.58	
$50,001 up to $70,000	14.97	15.79	
$75,001 or more	61.50	3.16	

Table 7: Comparison of general health and HRQOL across ethnicity at base line (age<65)

Variable	Caucasian (n=192)	AA (n=138)	P value
General Health			
Physical functioning	70.00 (17.40)	56.08 (23.33)	<.0001
Role-physical	84.74 (31.35)	61.34 (44.64)	<.0001
Emotional function	76.90 (36.89)	66.67 (44.10)	.0389
Vitality	68.29 (22.27)	59.06 (22.40)	.0010
Mental health	75.87 (18.91)	70.26 (68.93)	.0199
Social function	84.79 (22.03)	70.92 (28.08)	<.0001
Bodily pain	88.68 (20.73)	68.93 (29.45)	<.0001
General health	71.69 (22.54)	61.52 (24.42)	.0005
UCLA Prostate Cancer Index			
Urinary function	90.82 (19.49)	87.34 (18.35)	.1436
Bowel function	89.93 (12.56)	83.66 (15.41)	.0003
Sexual function	61.61 (27.62)	57.45 (28.25)	.2308
Urinary bother	87.63 (22.09)	80.36 (26.44)	.0144
Bowel bother	91.67 (17.95)	85.46 (23.24)	.0131
Sexual bother	69.59 (36.18)	55.93 (39.82)	.0039

Table 8: Comparison of general health and HRQoL at 3 month (age< 65 yrs)

Variable	UPHS (n=172)	VA (n=79)	p value
General Health			
Physical functioning	63.87 (18.44)	45.14 (25.31)	<.0001
Role-physical	52.87 (45.79)	38.60 (44.56)	.0331
Emotional function	71.85 (41.46)	56.86 (45.73)	.0178
Vitality	64.36 (21.16)	51.36 (26.14)	.0001
Mental health	77.38 (17.17)	70.51 (21.37)	.0116
Social function	74.83 (25.54)	65.07 (28.37)	.0122
Bodily pain	79.13 (24.71)	64.19 (29.98)	.0001
General health	74.93 (20.38)	53.55 (23.20)	<.0001
UCLA Prostate Cancer Index			
Urinary function	54.20 (30.70)	68.48 (30.69)	.0016
Bowel function	87.40 (16.66)	78.57 (19.84)	.0007
Sexual function	23.82 (22.95)	30.86 (28.06)	.0521
Urinary bother	58.61 (33.67)	65.58 (33.51)	.1551
Bowel bother	88.74 (20.95)	78.99 (27.33)	.0041
Sexual bother	31.68 (33.26)	38.43 (38.52)	.1922

Table 9: Comparison of general health and HRQoL at 3 month (age <65 yrs)

Variable	Caucasian (n=171)	AA (n=80)	p value
General Health			
Physical functioning	62.01 (20.23)	49.58 (24.82)	.0001
Role-physical	54.56 (45.46)	34.93 (43.87)	.0032
Emotional function	73.87 (39.94)	52.45 (46.90)	.0006
Vitality	62.88 (22.65)	54.84 (24.67)	.0177
Mental health	77.08 (17.81)	71.34 (20.35)	.0340
Social function	75.59 (25.10)	63.91 (28.55)	.0023
Bodily pain	80.529 (23.56)	61.41 (30.26)	<.0001
General health	73.12 (21.59)	57.96 (24.00)	<.0001
UCLA Prostate Cancer Index			
Urinary function	56.83 (30.87)	62.54 (32.16)	.2074
Bowel function	86.64 (17.19)	80.42 (19.46)	.0170
Sexual function	23.40 (23.67)	31.53 (26.40)	.0238
Urinary bother	60.07 (32.87)	62.32 (35.58)	.6434
Bowel bother	88.09 (21.47)	80.63 (26.79)	.0277
Sexual bother	36.03 (35.71)	29.04 (33.35)	.1753

Table 10: Comparison of general health and HRQoL at 6 month (age <65 yrs)

Variable	UPHS (n=140)	VA (n=76)	p value
General Health			
Physical functioning	70.36 (16.68)	49.08 (25.58)	<.0001
Role-physical	81.65 (33.99)	47.33 (44.75)	<.0001
Emotional function	86.23 (31.13)	57.66 (46.91)	<.0001
Vitality	68.12 (21.93)	52.17 (27.79)	<.0001
Mental health	79.96 (16.62)	72.27 (19.63)	.0027
Social function	84.35 (23.70)	66.50 (30.90)	<.0001
Bodily pain	87.97 (19.17)	66.97 (30.17)	<.0001
General health	74.46 (21.11)	51.91 (25.13)	<.0001
UCLA Prostate Cancer Index			
Urinary function	71.17 (26.50)	69.28 (28.79)	.6299
Bowel function	88.74 (13.43)	77.13 (18.99)	<.0001
Sexual function	27.52 (22.61)	29.88 (26.07)	.4917
Urinary bother	75.18 (29.10)	65.79 (32.87)	.0319
Bowel bother	90.00 (21.16)	79.33 (29.74)	.0026
Sexual bother	31.80 (32.84)	34.67 (36.51)	.5607

Table 11: Comparison of general health and HRQoL at 6 month (age <65 yrs)

Variable	Caucasian (n=145)	AA (n=71)	p value
General Health			
Physical functioning	67.69 (19.30)	53.03 (25.68)	<.0001
Role-physical	79.90 (35.14)	48.94 (45.40)	<.0001
Emotional function	83.92 (33.30)	60.39 (46.89)	<.0001
Vitality	66.17 (23.91)	55.19 (26.45)	.0026
Mental health	79.79 (16.60)	72.18 (19.87)	.0035
Social function	82.69 (25.69)	68.84 (29.50)	.0005
Bodily pain	86.64 (21.23)	68.45 (29.25)	<.0001
General health	71.86 (22.45)	55.63 (26.50)	<.0001
UCLA Prostate Cancer Index			
Urinary function	70.94 (26.06)	69.60 (29.77)	.7356
Bowel function	87.52 (14.88)	78.82 (18.23)	.0002
Sexual function	27.17 (23.14)	30.72 (25.21)	.3063
Urinary bother	75.17 (28.43)	65.14 (34.19)	.0241
Bowel bother	88.97 (22.99)	80.71 (27.97)	.0227
Sexual bother	35.74 (34.39)	26.81 (33.02)	.0746

Table 12: Comparison of general health and HRQoL at 12 month (age <65 yrs)

Variable	UPHS (n=152)	VA (n=56)	p value
General Health			
Physical functioning	70.92 (16.40)	50.54 (26.49)	<.0001
Role-physical	85.69 (32.25)	46.76 (47.10)	<.0001
Emotional function	87.72 (29.14)	64.81 (44.12)	<.0001
Vitality	71.13 (20.58)	49.22 (27.05)	<.0001
Mental health	81.32 (14.07)	70.27 (18.62)	<.0001
Social function	87.17 (21.26)	64.29 (29.53)	<.0001
Bodily pain	86.81 (19.37)	66.79 (31.95)	<.0001
General health	73.98 (22.01)	54.55 (26.92)	<.0001
UCLA Prostate Cancer Index			
Urinary function	73.66 (24.15)	66.88 (31.04)	.0989
Bowel function	89.40 (12.97)	79.28 (21.57)	<.0001
Sexual function	34.72 (23.77)	21.85 (21.89)	.0007
Urinary bother	78.13 (27.64)	63.39 (36.30)	.0021
Bowel bother	90.46 (19.92)	73.21 (31.21)	<.0001
Sexual bother	33.50 (32.23)	26.44 (35.15)	.1854

Table 13: Comparison of general health and HRQoL at 12 month (age <65 yrs)

Variable	Caucasian (n=151)	AA (n=57)	p value
General Health			
Physical functioning	70.20 (17.15)	52.81 (26.59)	<.0001
Role-physical	85.00 (33.02)	50.00 (47.19)	<.0001
Emotional function	87.11 (29.61)	67.26 (43.80)	.0003
Vitality	70.20 (21.92)	52.08 (26.13)	<.0001
Mental health	81.16 (14.31)	70.88 (18.35)	<.0001
Social function	85.84 (22.48)	67.86 (29.57)	<.0001
Bodily pain	86.95 (20.36)	66.75 (29.93)	<.0001
General health	73.41 (22.84)	56.40 (26.15)	<.0001
UCLA Prostate Cancer Index			
Urinary function	73.28 (24.34)	68.02 (30.74)	.1989
Bowel function	88.52 (14.75)	81.80 (19.22)	.0078
Sexual function	33.13 (23.72)	26.65 (24.03)	.0862
Urinary bother	78.31 (27.64)	63.16 (36.01)	.0014
Bowel bother	89.74 (20.67)	75.44 (30.80)	.0002
Sexual bother	34.52 (33.53)	24.09 (30.79)	.0456

Table 14: Baseline Clinical Characteristics (age<65 yrs. n=153)

Variable		Percent
Marital Status	Married	77.24
	Single	10.34
	Widowed	0.69
	Divorced	11.72
Pre-hospital Living Arrangement		
	In community	75.68
	Lives alone	20.27
	Don ’t know	4.05
Health Insurance	Medicare	7.04
	Medicare/Managed Care	0.70
	Private	78.87
	None	13.38
TNM Stage of Cancer	T1a to T1c	67.59
	T2a to T2c	19.31
	T3a to T3b	13.10
Mean Charlson comorbidity score		3.79 (2.55)
Mean PSA at the time of diagnosis		7.69 (9.59)
Mean Gleason score at the time of diagnosis		6.34 (0.77)

Table 15: Treatment pattern (age<65 n= 153)

Treatment		Percent
Radiation	Yes	14.38
	No	85.62
Surgery	Yes	84.35
	No	15.65
Hormone Therapy	Yes	10.88
	No	89.12
Watchful Waiting	Yes	3.40
	No	96.60
Other Procedures	Yes	4.08
	No	95.92

Table 16: Baseline Clinical Characteristics Comparison by Ethnic group (age <65 yrs)

Variable	Caucasian (n=112)	African American (n= 41)	p value
Marital Status			? = 24.6
Married	84.91	56.41	p<.0001
Single	10.38	10.26	
Widowed	0.94	33.33	
Divorced	3.77		
Pre-hospital Living Arrangement			? = 16.79
In community	83.33	55.00	p=.0002
Lives alone	12.04	42.50	
Don ’t know	4.63	2.50	
Health Insurance			? = 29.95
Medic are	4.81	13.16	p<.0001
Medicare/Managed Care	0.96	0.00	
Private	89.42	50.00	
None	4.81	36.84	
TNM Stage of Cancer			? = 22.65
T1a to T1c	68.87	64.1	p=.2044
T2a to T2c	16.04	28.21	
T3a to T3b	15.09	7.69	
Mean Charlson Comorbidity score	3.6 (2.62)	4.16 (2.37)	p=.3000
Mean PSA at time of diagnosis	6.98 (7.48)	9.59 (13.76)	p=.1472
Mean Gleason score at time of diagnosis	6.32 (0.62)	6.38 (1.09)	p=.7221

Table 17: Comparison of Treatment Pattern by Ethnic group (age <65 yrs)

Treatment		Caucasian (n= 112)	African American (n=41)	p value
Radiation	Yes	9.43	27.50	? = 7.69
	No	90.57	72.50	p=.0055
Surgery	Yes	90.65	67.50	? = 11.83
	No	9.35	32.50	p=.0006
Hormone Therapy	Yes	6.54	22.50	? = 7.64
	No	93.46	77.50	p=.0057
Watchful Waiting	Yes	3.74	2.50	? = .1359
	No	96.26	97.50	p=.7124
Other Procedures	Yes	4.67	2.50	? =.3511
	No	95.33	97.50	p=.5535

Table 18: Overall satisfaction with care (age < 65 years)

Variable	% 3 Months n=251	% 6 Months n=216	% 12 Months n=208
How would you rate the service you have received?			
Poor	1.88	1.43	1.46
Fair	3.76	3.33	2.43
Good	32.86	35.71	33.50
Excellent	61.50	59.52	62.62
Did you get the kind of service you wanted?			
No, definitely	0.47	0.00	0.49
No, not really	5.19	3.79	3.40
Yes, generally	35.38	38.86	33.50
Yes, definitely	58.96	57.35	62.62
To what extent has our program met your needs?			
None of my needs have been met	0.96	0.97	1.49
Only a few of my needs have been met	5.77	6.67	4.46
Most of my needs have been met	34.13	30.43	36.14
Almost all of my needs have been met	59.13	61.84	57.92
If a friend were in need of similar help, would you recommend our program to him or her?			
No, definitely not	0.95	0.97	0.49
No, I don't think so	3.33	1.46	1.97
Yes, I think so	24.29	24.27	21.18
Yes, definitely	71.43	73.30	76.35
How satisfied are you with the amount of help you have received?			
Quite dissatisfied	0.94	2.38	1.95
Indifferent or mildly dissatisfied	4.23	5.71	3.90
Mostly satisfied	33.80	34.29	36.10
Very satisfied	61.03	57.62	58.05
Have the services you received helped you to deal more effectively with your problems?			
No, they seemed to make things worse	0.00	0.48	0.00
No, they really didn't help	4.76	5.24	5.83
Yes, they helped somewhat	30.00	26.19	35.44
Yes, they helped a great deal	65.24	68.10	58.74
In an overall sense, how satisfied are you with the service you have received?			
Quite dissatisfied	3.30	2.37	1.46
Indifferent or mildly dissatisfied	5.66	5.69	5.37
Mostly satisfied	33.96	31.28	33.17
Very satisfied	57.08	60.66	60.00
If you were to seek help again, would you come back to our program?			
No, definitely not	0.96	0.47	1.48
No, I don't think so	2.87	4.27	2.96
Yes, I think so	28.23	26.54	24.14
Yes, definitely	67.94	68.72	71.43

Table 19: Satisfaction with care comparison by ethnicity (age<65)

Variable	3 month			6 month			12 month		
	AA n=80	Cauca. n=171	P value	AA n=71	Cauca. n=145	P value	AA n=57	Cauca. n=151	P value
How would you rate the service you have received?									
Poor	2.82	1.41	0.4076	1.47	1.41	0.2728	1.79	1.33	0.2138
Fair	2.82	4.23		5.88	2.11		1.79	2.67	
Good	39.44	29.58		41.18	3.10		44.64	29.33	
Excellent	54.93	64.79		51.47	63.38		51.79	66.67	
Did you get the kind of service you wanted?									
No, definitely	0.00	0.71	0.4201	0.00	0.00	0.1478	1.79	0.00	0.0143
No, not really	5.63	4.96		4.35	3.52		0.00	4.67	
Yes, generally	42.25	31.91		47.83	34.51		46.43	28.67	
Yes, definitely	52.11	62.41		47.83	61.97		51.79	66.67	
To what extent has our program met your needs?									
None of my needs have been met	2.90	0.00	0.0548	1.47	0.72	0.3316	1.85	1.35	0.0142
Only a few of my needs have been met	5.80	5.76		10.29	5.04		9.26	2.70	
Most of my needs have been met	42.03	80.22		33.82	28.78		48.15	31.76	
Almost all of my needs have been met	49.28	64.03		54.41	65.47		40.74	64.19	
If a friend were in need of similar help, would you recommend our program to him or her?									
No, definitely not	2.90	0.00	0.1467	1.49	0.72	0.3745	1.82	0.00	0.0743
No, I don't think so	1.45	4.26		1.49	1.44		0.00	2.70	
Yes, I think so	26.09	23.40		31.34	20.86		29.09	18.24	
Yes, definitely	69.57	72.34		65.67	76.98		69.09	79.05	
How satisfied are you with the amount of help you have received?									
Quite dissatisfied	2.82	0.00	0.1045	4.41	1.41	0.1613	3.57	1.34	0.1397
Indifferent or mildly dissatisfied	2.82	4.93		2.94	7.04		1.79	4.70	
Mostly satisfied	39.44	30.99		41.18	30.99		46.43	32.21	
Very satisfied	54.93	64.08		51.47	60.56		48.21	61.74	
Have the services you received helped you to deal more effectively with your problems?									
No, they seemed to make things worse	0.00	0.00	0.9342	0.00	0.70	0.8660	0.00	0.00	0.2899
No, they really didn't help	4.29	5.00		5.88	4.93		1.79	7.33	
Yes, they helped somewhat	31.43	29.29		27.94	25.35		39.29	34.00	
Yes, they helped a great deal	64.29	65.71		66.18	69.01		58.93	58.67	
In an overall sense, how satisfied are you with the service you have received?									
Quite dissatisfied	4.23	2.84	0.0984	4.35	1.41	0.1615	3.57	0.67	0.0182
Indifferent or mildly dissatisfied	7.04	4.96		7.25	4.93		1.79	6.71	
Mostly satisfied	43.66	29.08		37.68	28.17		46.43	28.19	
Very satisfied	45.07	63.12		50.72	65.49		48.21	64.43	
If you were to seek help again, would you come back to our program?									
No, definitely not	0.00	1.42	0.0113	0.00	0.71	0.4791	3.57	0.68	0.0365
No, I don't think so	0.00	4.26		5.71	3.55		0.00	4.08	
Yes, I think so	41.18	21.99		31.43	24.11		33.93	20.41	
Yes, definitely	58.82	72.34		62.86	71.63		62.50	74.83	

Table 20: Indirect cost comparison by ethnicity (age<65 years)

Variable	3 month			6 month			12 month		
	AA (n=80)	Cauca. (n=171)	P value	AA (n=71)	Cauca. (n=145)	P value	AA (n=57)	Cauca. (n=151)	P value
Have you incurred (in the last 3 month) out of pocket expense for non-prescribed medication? YES NO	44.00 56.00	47.62 52.38	.758	34.29 65.71	43.21 56.79	0.369	48.65 51.35	41.46 58.54	0.464
Mean Monthly average expenses on prescribed meds (std)	50.0 (55.7)	38.7 (37.6)	.467	35.9 (50.7)	51.1 (51.9)	.385	43.8 (66.1)	48.9 (48.9)	.771
Mean Monthly average expenses on non-prescribed meds (std)	22.0 (37.8)	14.3 (24.9)	.437	18.9 (25.0)	34.3 (139)	.707	30.1 (34.2)	100.9 (479)	.572
Mean other monthly average expense related to prostate cancer (std)	746 (2348)	136 (213)	.044	84.8 (153)	93.4 (468)	.918	100.3 (383)	9.7 (24.7)	.039
Do you take more time for traveling? YES NO	34.78 65.22	9.38 90.63	.004	28.13 71.88	11.25 88.75	0.028	34.29 65.71	13.58 86.42	0.010
Do you miss work or have decreased your work hours? YES NO	41.67 58.33	41.27 58.73	.973	20.00 80.00	17.50 82.50	0.749	15.15 84.85	8.54 91.46	0.294
Do you now take more time to do the usual housework? YES NO	41.67 58.33	23.08 76.92	.083	. 34.29 65.71	12.20 87.80	0.005	43.24 56.76	7.41 92.59	< .0001
Do you now need mode help from your caregivers? YES NO	29.17 70.83	15.63 84.38	.152	18.18 81.82	4.94 95.06	0.023	13.89 86.11	4.88 95.12	0.089

Task 6: Indirect Cost Data Abstraction Design - completed

A survey to obtain indirect cost data was developed and this survey is sent out with each follow-up to obtain indirect cost data. The data entry and analysis is currently ongoing.

Task 7: Abstraction of Medical Records - continued

a. Medical record abstraction is complete for those who have completed 6 months into the study (n=153). The results are presented in Tables 15-18. For rest of the participants, medical record abstraction is currently being performed and will continue during the follow-up periods.

b. Data entry and quality control measures are ongoing.

Task 9: Data entry and coding - continued

a. Data dictionary was created

b. Databases were set up in Microsoft Access and Excel

c. All the data obtained is being coded and entered (ongoing).

Task 10: Interim Analysis, Months22-24 - ongoing

a. Interim statistical analyses of data will be performed periodically

b. Second annual report will be written.

Task 11:Cost-Effectiveness Model, Moth 30-3 - continued

a. Cost-Effectiveness analysis and Markov decision model will be developed.
b. Simulation results will be obtained.

Task 12: Interim Analyses and final analysis- Months 18-36 - continued

a. Interim statistical analyses will be performed at the second year of the study. The final analyses will be performed during 3rd year of the study.

Task 13: Publishable reports will be developed – Months 30-36

This task is currently ongoing. With the help ofpreliminarydata, we have developed four manuscripts, three been published and one is under review. We have also presented six peer reviewedabstracts at the various conferences. Additionally, four more manuscripts are under preparation.

KEY RESEARCH ACCOMPLISHMENTS

During the study period between 2/1/2005 to 1/31/2006, we have established an effective recruitment and follow up mechanism. We have successfully completed recruited of total 330 newly diagnosed, younger (< 65 yrs.) prostate cancer patients from the urology clinic, radiation oncology clinic of the University of Pennsylvania and VA Medical Center. Patient recruitment as well as data collection on Health Related Quality of Life, Satisfaction with Care, Direct and Indirect medical cost at baseline and follow-up is ongoing. During this report period, we have achieved an overall retention rate of 84%. Using our preliminary data, we have developed four manuscripts, three of which are published and one is under review. We have presented the results in six conferences. We have secured a NCI grant using SEER-Medicare data to analyze the ethnic variations health resource utilization and cost.

REPORTABLE OUTCOMES

Manuscripts:

(1). Jayadevappa R, Chhatre S, Weiner M, Bloom BS, S Malkowicz B,. Medical Care Cost of Patients with Prostate Cancer. Urologic Oncology: Seminars and original Investigations, 23 (2005): 155-162.

(2) Jayadevappa R, Bloom BS, Chhatre S, Fomberstein KM, Wein AJ, S Malkowicz B. Health Related Quality of Life and Direct Medical Care cost in newly diagnosed younger men with prostate cancer. The Journal of Urology, 2005, 174:1059-1064.

(3) Jayadevappa R, Chhatre S, Whittington R, Bloom BS, Wein AJ, S Malkowicz B. Health Related Quality of Life and Satisfaction with Care among Older Men Treated with Radical Prostatectomy or External Beam Radiation Therapy. BJU International (in Press).

(4) Jayadevappa R, Chhatre S, Bloom BS, Wein AJ, S Malkowicz B. Ethnic Differences in Health Related Quality of Life and Satisfaction with Care among Older Men with Prostate Cancer (under review).

Working Manuscripts: (under preparation)

1.Jayadevappa R, Malkowicz SB, Chhatre S, Bloom BS. Differences in Satisfaction with Care Between Treatments for Newly Diagnosed Prostate Cancer Patients
2.Jayadevappa R, Malkowicz SB, Chhatre S, Bloom BS. Health Related Quality of Life and Cost of Care of older Prostate Cancer Patients.
3.Jayadevappa R, Bloom BS, Malkowicz SB Chhatre S. Variations in Health Related Quality, satisfaction with care and direct medical care cost of newly Diagnosed Prostate Cancer Patients Across Ethnicity.
4. Jayadevappa R, Bloom BS, Malkowicz SB Chhatre S, Treatment pattern and Health Related Quality of Life of VA and non-VA prostate cancer patients.

I. Peer Reviewed Abstract:

1. Jayadevappa R, Chhatre S, Wein AJ, Malkowicz SB. (2006). Ethnic Difference in Health Related Quality of Life and Satisfaction with care of Newly Diagnosed Prostate Cancer Patients. JAGS (acceptred).
2. Jayadevappa R, Chhatre S, Bloom BS, Wein AJ, Malkowicz SB. (2005). Health Related Quality of Life of Direct Medical Care of Newly Diagnosed Prostate Cancer Patients. AcademyHealth-Annual Research Conference.
3. Jayadevappa R, Chhatre S, Johnson K, Bloom BS, Malkowicz SB. (2004). Quality of Life of Newly Diagnosed Prostate Cancer Patients. AcademyHealth-Annual Research Conference.
4. Jayadevappa R, Chhatre S, Rosner A, Fimberstein K, Bloom BS, Malkowicz SB (2004). Quality of Life of newly diagnosed Elderly Prostate Cancer Patients. Journal the American Geriatrics Society.
5. Jayadevappa R, Chhatre S, Rosner A, Fimberstein K, Johnson K, Bloom BS, Malkowicz SB. (2004). Quality of life of newly diagnosed prostate cancer patients in a public vs. private setting. Value in Health, 7 (3):253.
6. Jayadevappa R, Malkowicz SB, Chhatre S, Weiner M, Bloom BS (2003). Cost of Care of Patient with Prostate Cancer Across Age and Ethnicity. The Journal of Urology, 169 (4): 15.

Grants:

1.Principal Investigator – Variations in Health Resource Utilization and Cost of Care of Prostate cancer. 1/1/06-12/31/08.

CONCLUSIONS

Most of the proposed targeted activities have been achieved during the study period. We have a well-established recruitment and retention mechanism in place. The support of Urologist has been very helpful toward this. As of now, we have recruited 330 newly diagnosed younger prostate cancer patients and our overall retention rate is currently higher than 84%. Most of the data has been entered, with established quality control measures. We have completed the preliminary analysis. Once all the chart abstraction and follow-up is complete we will perform the final analysis. Also, after we obtain all the cost and HRQoL data, we will develop cost-effectiveness model. In addition, we have been able to publish and present the preliminary results (please see Appendix).

APPENDIX

Articles

(1) Ethnic Differences in Health Related Quality of Life and Satisfaction with Care of Newly Diagnosed Elderly Prostate Cancer Patients (under review)

(2) Health Related Quality of Life and Satisfaction with Care among Older Men Treated with Radical Prostatectomy or External Beam Radiation Therapy. British Journal of Urology International (in press).

(3) Medical Care Cost of Patients with Prostate Cancer. Urologic Oncology: Seminars and Original Investigations, 23 (2005): 155-162.

(4) Health Related Quality of Life and Direct Medical Care cost in newly diagnosed younger men with prostate cancer. The Journal of Urology, 2005, 174:1059-1064.

(5) Health Related Quality of Life and Direct Medical Care of Prostate Cancer patients. Abstract Presented at the 2005 AcademyHealth Annual Conference

Title: Ethnic Differences in Health Related Quality of Life and Satisfaction with Care of Newly Diagnosed Elderly Prostate Cancer Patients

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ABSTRACT

Objective: We compared Health Related Quality of Life (HRQoL), satisfaction with care and treatment of newly diagnosed older PCa patients by ethnicity.

Methods: Prospective cohort study design was used to recruit 104 older (? 65 yrs) PCa patients from an urban academic hospital and a VA hospital.Patients completed generic (SF-36) and PCa specific (UCLA-PCI) HRQoL and satisfaction with care (CSQ-8) instruments prior to treatment and at 3, 6 and 12 months of follow-up. Demographic and clinical data were obtained via medical chart review. Demographic and clinical characteristics were comparedLogistic regression and Kaplan Survival curves were used to analyze association of race with return to baseline values (RBV) and compare mean number of days to RBV of generic and PCa specific HRQoL.

Results: Caucasians had significantly higher income, education and better general health. Subscale scores of generic HRQoL at baseline were significantly higher for Caucasians. Age (OR=0.5, CI=.32-.82), non-VA hospital (OR=28.8, CI=2-4.02) and PSA score at diagnosis (OR=2.8, CI=1.05-7.5) were associated RP treatment. Caucasians required less time to RBV compared with African Americans for physical function (OR=0.59), role physical (OR=0.73), role emotional (OR=0.68), social function (OR=0.59), bodily pain (OR=0.68), general health (OR=0.64), urinary function (OR=0.69), bowel function (OR=0.66), sexual function (OR=0.63), bowel bother (OR-0.62) and sexual bother (OR=0.56). Satisfaction with care at all times was comparable across ethnicity.

Conclusions: Significant ethnic differences exist in socio-demographic characteristics and treatment received. Older African Americans appear to take more time to reach their baseline HRQoL values post-treatment compared to older Caucasian patients.

Key Words: Prostate cancer; Ethnicity; Health Related Quality of Life; Satisfaction with care

INTRODUCTION

Prostate cancer (PCa) is the leading cancer diagnosed among elderly men in the U.S. with a median age at diagnosis of 72 years (1). Ethnicity plays an important role in PCa diagnosis, treatment and outcomes (1-17). Due to uncertainty in screening and treatment of PCa, debate on outcomes such as Health Related Quality of Life (HRQoL) and satisfaction with care continues (1-9). As the American population ages and as screening for PCa becomes more widespread, it is expected that more number of elderly will be diagnosed with an early stage of PCa. This has significant implications for HRQoL and satisfaction with care due to increased future morbidity and mortality burden of PCa (6). Despite the expanding literature on disparity in treatment, little is known about the effects of PCa treatment on HRQoL among elderly African Americans. We analyzed the role of ethnicity in curative treatment pattern, and compared recovery pattern of generic and PCa specific HRQoL and satisfactionwith care between elderly African American and Caucasian with newly diagnosed PCa.

METHODS

Prospective cohort design was used to assess and compare treatment pattern and HRQoL of older (= 65 yrs) PCa patients (n=104). The study was part of a larger prospective cohort study and was approved by the institutional review board. All personnel involved in the study completed subject protection training and met the appropriate health information portability and accountability act (HIPAA) education requirements before engaging in this research. After obtaining informed consent and HIPAA from participants, baseline data on generic and prostate specific HRQoL was obtained prior to treatment. Structured medical chart review was used to collect data on patient demographics (age, ethnicity, education, date of PCa diagnosis and health insurance) and clinical characteristics (treatment type, PSA at diagnosis, Gleason score, TNM stage, follow-up PSA and comorbidity). To assess generic and prostate specific HRQoL and satisfaction with care, participants completed self-administered instruments during enrollment (baseline) and at three, six and 12 months of follow-up. Prostate cancer treatment was classified as radical prostatectomy (mono-therapy and multimodel therapy) andradiation therapy (mono-therapy and multimodel therapy).

Prostate specific HRQoL was assessed using the UCLA Prostate Cancer Index (PCI) that is a comprehensive self-administered 20 item questionnaire that quantifies PCa specific HRQoL in six domains (urinary function, urinary bother, sexual function, sexual bother, bowel function, and bowel bother). PCI has performed well in older population, demonstrated good psychometric properties and appeared easy to understand and complete (18). It is a reliable and valid measurement of HRQoL among older patients with early stage PCa. Generic quality of life was measured using the Medical Outcome Study Short Form (SF-36). This instrument was designed for use in clinical practice, research, health-policy evaluation and population surveys (19). It is a single multi-item scale that assesses eight health concepts: physical limitation caused by health problems, limitations on social activities caused by physical/emotional problems, role

limitations caused by physical health problems, and emotional problems, bodily pain, general mental health, vitality, and general health perceptions. It was constructed for self-administration or for administration by a trained interviewer, either in person or by telephone and was tested for reliability and validity. Maximum possible score for each subscale is 100% and minimum is 0%. Higher score on SF-36 and PCI indicates higher quality of life. Patient's satisfaction with care was measured using self-administered Client Satisfaction Questionnaire (CSQ-8). This questionnaire has been extensively studied and demonstrated good psychometric properties (20). A higher score on CSQ-8 indicates greater patient satisfaction with care. Baseline Charlson comorbidity index (CHS) was computed using ICD9 codes for all inpatient and outpatient events. This data was obtained from hospital based administrative databases (PICARD). Charlson comorbidity index is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of illness burden (21).

Subject recruitment and selection:

Participants: Study participants were elderly (= 65 years) African American and Caucasian men diagnosed for PCa within four months prior to or after the inception of the study. Newly diagnosed PCa cases were identified and recruited at the urology clinics of an academic medical center and the Veterans Administration Medical Center (VA). A patient was ineligible if he had visited for a second opinion only and not for continued care, was medically unstable or disoriented and/or if he was unable to communicate in English.

Recruitment: Initial information about study was provided to the potential participants by their urologists during clinic visits and later contacted by the study research assistant if they expressed an interest. Additionally, attendees of the weekly prostatectomy orientation class organized at the urology clinics were contacted. At this stage, a potential participant could agree to participate in the study and complete the consent form. In case a person was interested but wanted to be contacted later, the research assistant did so. During telephone consent interview contact, if the

potential participant agreed to participate, he was mailed a consent form along with a stamped return envelope. Participants were asked to discuss the consent form with the research assistant prior to signing.

Retention Plan: During study enrollment, participants were informed about the importance of continued and active participation. Non-respondents to the mail-in surveys were followed up by a telephone call after 10 days. Finally, non-responders were encouraged by their urologists to continue participation. In case of non-response due to death, the cause of death (prostate or non-prostate) was noted.

***Statistical* Analysis:** Demographic and clinical variables were compared by ethnicity using-test and chi-square. To study the association between treatment and ethnicity, we used sequential logistic regression. First, ethnicity was the only independent variable in the model to predict treatment. Next, age, Charlson comorbidity score, general health, physical health, difficulty/discomfort urinating, pain/aches in back, hips or legs and stage of cancer were introduced. A change of 5-10 points in score on HRQoL scale (generic or prostate-specific) was considered clinically significant (19, 22). Mean HRQoL at baseline and at three, six and 12 month were compared by ethnicity. During follow-up period, a participants is considered as having 'returned to baseline' for a given HRQoL domain, if the differences in scores between baseline and follow-up is less than or equal to seven points. We compared proportion of 'return to baseline' at three, six and 12 months by ethnicity for all HRQoL subscales. Log-linear backward stepwise regression was used to determine predictors of 'number of days to return to baseline' for prostate-specific and generic domains. Covariates were age, ethnicity, income, CHS, marital status, education, baseline score, treatment, hospital type and TNM group. Following variables were dichotomized: race (1=White, 0= African American); marital status (1=married, 0=other); education (1=H.S. or less, 0= > H.S.); treatment group (1=radical prostatectomy, 0= radiation therapy); hospital type (1=non-VA, 0=VA) and TNM group (1=T1a

to T2a, 0=T3a to T3b). We used Kaplan Survival analysis to compare mean number of days to return to baseline for all HRQoL subscales.

RESULTS

Demographics, signs and symptoms of the study population are presented in Table 1. Majority of the Caucasian participants were college-educated, married and had an annual income of $40,000 or more. The difference in mean age at diagnosis was statistically significant. Mean CHS was comparable by ethnicity. Prostate specific signs and symptoms were comparable across ethnicity, except for pain/aches in back, hips or legs, which was reported by higher proportion of African Americans.

Table 1 shows the clinical characteristicsof participants at diagnosis and treatment. Clinical and pathologic stages ranged from T1N0M0 (clinically inapparent tumor not palpable or visible by imaging [T1], no regional lymph node metastatsis [N0], and no distant metasis [M0]) to T3bN0M0 (tumor extends through prostate capsule [T3], no regional lymph node metasis [N0], and no distant metastasis [M0]). Tumors were moderately differentiated with a mean Gleason score of 6.3 (.94) for Caucasians vs. 5.9 (1.7) for African Americans (p=.2830). Also, PSA score and stage of cancer at the time of diagnosis were comparable between groups. However, treatment pattern differed by ethnicity. Higher proportion of African Americans received radiation, whereas higher proportion of Caucasian received surgery (p=.0148) African Americans reported significantly higher level of post treatment PSA than Caucasians.

Logistic regression was used to test the association between treatment and ethnicity, after adjusting for covariates sequentially (not reported). First, the OR for ethnicity was 16.7 (95% CI 2.1–135). As age, Charlson comorbidity score, baseline general health status, baseline physical function, stage of cancer and hospital type were introduced, the OR associated with ethnicity reduced to 3.8 (95% CI 0.34 – 43). Once hospital type was introduced, ethnicity seized to be a significant predictor of treatment. A non-VA patient was 10.8 times more likely to receive surgery than a VA patient.

Baseline HRQoL: A comparison of baseline generic and prostate specific HRQoL showed that groups were comparable except for role emotional and general health. Groups also had comparable prostate specific HRQoL.

Generic HRQoL: Pattern of post-treatment progression of mean scores for physical function was comparable by ethnicity. After an initial decline at three months, the scores improved and were almost equal to baseline values by 12 months. For role physical, the drop in scores at three months was greater for Caucasians. The scores improved thereafter and by 12 months, were close to baseline values. Both ethnic groups had a drop in role emotional scores at three months. The scores improved thereafter for Caucasians, for African Americans, scores improved by six month and declined by 12 months. For vitality, scores at three monthswere lower than baseline levels for both groups. For Caucasians, the scores improved continuously thereafter, for African Americans, scores remained at three months level. At baseline, the scores on mental health were higher for Caucasians. By three months, the Caucasian group saw a decline in scores that improved by 12 months. For African Americans, scores continued to improve and were higher than baseline value by 12 months. For social function, both groups had an initial decline at three months. While the scores improved thereafter for Caucasians, for African Americans, there was a drop at 6 month followed by an improvement. Pattern of progression for score on bodily pain was comparable between groups. General health for Caucasian declined slightly at thee month and remained unchanged thereafter. For African Americans, scores had small variation over 12 month period.

Urinary function consists of five items and urinary bother consists of one item. Bowel function consists of four items (rectal urgency, loose stools, distress with bowel movement and abdomen pain) and bowel bother has one item. PCI measures sexual function by combining eight items and sexual bother by one item. For Caucasians, score on urinary function at 12 months was lower than baseline level. For African Americans, after a decline at three and six month, the score improved. Mean score on bowel function at 12 months was lower for African Americans. The pattern of progression was similar for sexual function. After declining at three and six months, the scores improved somewhat, however by 12 month they remained lower than baseline values. Caucasians showed better improvement in scores on urinary bother by 6 months. By 12 months, both groups were comparable. The progression of scores on bowel bother was

fairly constant for Caucasians. For African Americans, scores improved after an initial decline. Finally, scores on sexual bother declined over 12 months for both groups.

During follow-up period, a participant is considered as having 'returned to baseline' for if the difference in HRQoL scores between baseline and follow-up is equal to seven points or less. Table 2 shows the comparison of return to baseline at 12 month. It is observed that for PCa specific HRQoL, higher proportion of Caucasians returned to baseline by third month for bowl bother, and higher proportion of Caucasians returned to baseline by six month for sexual bother. For generic HRQoL, higher proportion of Caucasians returned to baseline on role physical, role emotional, social function and bodily pain.

Results of log-linear backward regression to determine factors associated with 'time to return to baseline' for generic and prostate specific HRQoL is presented in Table 3. Covariates are Charlson comorbidity score, PSA score, hospital type, race, treatment type, marital status, age, TNM stage of cancer and baseline score. Baseline score was associated with time to return to baseline for physical function (OR=1.01), role physical (OR=1.01), role emotional (OR=1.03), vitality (OR=1.52), mental health (OR=1.01), social function (OR=1.01), bodily pain (OR=1.01) and general health (OR=1.02). It was also associated with time to return to baseline for urinary function (OR=1.01), sexual function (OR=1.01), urinary bother (OR= 1.01) and sexual bother (OR=1.01). Caucasians required less time to return to baseline than African Americans for physical function (OR=0.59), role physical (OR=0.73), role emotional (OR=0.68), social function (OR=0.59), bodily pain (OR=0.68), general health (OR=064), urinary function (OR=0.69), bowel function (OR=0.66), sexual function (OR=0.63), bowel bother (OR=0.62) and sexual bother (OR=0.56). Higher TNM stage of cancer was associated with longer time to return to baseline for physical function (OR=1.99), roleemotional (OR=1.88), vitality (OR=1.01), social function (OR=1.75), general health (OR=1.58), bowel function (OR=2.01) and bowel bother (OR=2.18).

DISCUSSION

Prostate cancer is the most commonly diagnosed cancer in elderly male and could significantly impact the health care system, as the population ages. Race/ethnicity plays an important role in the observed variation in treatment and affects cancer recurrence and outcome in elderly (8-16). In this study we evaluated the impact of differential treatments received by older African American and Caucasian PCa patients on outcomes such as HRQoL and satisfaction with care. Main findings of this study are: a) African American elderly patients take longer time to return to their baseline scores of generic and prostate specific HRQoL compared to Caucasian elderly patients; b) Caucasian patients reported improvement by 12 months for most of generic HRQoL domains and prostate-specific HRQoL domains (urinary function, bowel function, urinary bother, bowel bother and sexual bother); c) TNM stage of cancer and hospital type (non-VA hospital) was associated with treatment; and e) there was no significant ethnic difference in satisfaction with care at any time.

The incidence of cancer among African American men is 272.1 per 100,000, 39 percent greater than Caucasian men (1). African Americans with PCa have poorer stage-specific survival than Caucasians and have a higher rate of presentation with late stage disease (1,15,23). Treatment patterns differ by ethnicity (13, 23-25). Mortality rate increases with age and age has strong influence on treatment patterns. Younger men prefer radical prostatectomy, middle-aged men prefer radiation therapy and older men prefer either no treatment or hormone therapy (1,3,15). A cohort study using SEER data showed that African Americans were 64% less likely to receive radical prostatectomy than Caucasians for localized PCa (9). For localized and regional disease stages, Caucasian men are more likely to receive prostatectomy than African American men who are more likely to receive radiation therapy (9,10,25).

Our log-linear backward stepwise regression demonstrated that ethnicity/race was an independent predictor of several of 'time to return to baseline values' of generic and prostate specific HRQoL scales. Using CaPSURE database, Lubeck et al showed significant differences in clinical presentation, socio-demographics and HRQoL between black and white PCa patients. Also, the HRQoL differences persisted at one year post-treatment (8). African Americans receiving radical prostatectomy often exhibited more adverse pathological features than Caucasians (26). In a prospective study, Johnson et al found that among prostatectomy patients, African Americans reported better recovery of sexual and urinary function at five years post-diagnosis and more problems with sexual function than Caucasians. However, racial/ethnic differences in recovery among radiation therapy patients was only limited (16). Though the study used a large sample from SEER sites, it did not account for bias in selection and many important clinical variables (PSA and TNM stage) were not reported. Unlike our study, Gleason score showed significant variation across race/ethnicity. Although time equalizes some of HRQoL between groups, African American elderly may take more time to recover in the beginning period as shown in our study. Also, as we reported, at 12 months of follow-up, African American elderly took significantly longer time to recover to baseline values for generic (physical function, role emotional and bodily pain) and prostate specific (bowel bother and sexual) HRQoL. In a prospective study, Knight et al, observed similarities in preferences, optimism, involvement in care, and differences in quality of life (nauseas and vomiting, sexual interest and weight gain) measures between black and white veterans (27).

CONCLUSIONS

Elderly men with early stages of PCa often live long post-diagnosis and treatment, and desire to maximize the quality of their life. The relationship of race/ethnicity and PCa with regard to prognosis for outcomes such as HRQoL and satisfaction with care continues to be controversial (8-14, 16). Ours is a first study to use prospective, longitudinal design (from a single non-VA and VA institution) to evaluate the impact of curative treatment on outcomes such as HRQoL and satisfaction with care of elderly PCa patients from two ethnic groups. We observed that curative treatments of early stage PCa showed differential outcomes by ethnicity for generic and prostate specific HRQoL. African American elderly were more likely to take longer time to return to their baseline function. Also, higher percentage of them did not return to baseline score by 12 months, compared to Caucasian elderly. Comprehensive assessment (clinical, socioeconomic, demographic, and environmental) of elderly PCa patients is needed to identify the factors associated with optimal outcomes. Physicians cannot assume that outcomes among African American and Caucasian elderly are similar and thus treatment must be individualized to target HRQoL domains that can be improved more effectively. This has implications for effective management of PCa in elderly from different race/ethnic groups and merits further research.

Limitations: The study limitations are: (1) Due to the absence of randomization the study results may not be representative of all older PCa patients receiving treatments. Also, there is potential for inherited treatment bias. (2) The follow-up period was short term (12 months); (3) Sample is limited to two large health care systems and may not be representative of the general elderly population.

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Table 1: Demographics, signs and symptoms, clinical characteristics and treatment received

Covariates	Caucasians (n=80)	AA (n= 24)	P value
Age (mean ± std)	69.0± 4.0	71.6±5.7	.034
Charlson comorbidity (mean ± std)	1.6±2.3	1.9±2.7	.680
Education (%)			
HS or less	30.30	77.78	.0003
College or more	69.70	22.22	
Marital Status (%)			
Single/Widowed/Div	18.18	55.56	.0014
Married	81.82	44.44	
Employment Status (%)			
Full-time	15.15	11.11	.664
Part-time/other	84.85	88.89	
Income Level (%)			
> $40,000	68.25	5.56	<.0001
? $40,000	31.75	94.44	
Hospital Type			
Non-VA	80.60	16.67	.0004
VA	19.40	83.33	
Signs and symptoms (%)			
Difficulty or discomfort urinating	20.90	33.33	.2694
Having to urinate too often	46.97	72.22	.0572
Weak urinary stream	43.94	44.44	.9695
Infection of bladder or prostate	8.96	5.88	.6822
Blood in urine	6.06	5.56	.9360
Pain or aches in back, hips or legs	27.27	77.78	<.0001
More tired or worn out than usual	24.24	38.89	.2167
PSA-at diagnosis (ng/ml) (Mean± std.)	8.3 ± 9.9	9.2± 7.7	.6774
PSA-post treatment (ng/ml)(Mean ± std.)	0.3±.58	1.7±1.7	<.0001
Gleason score (total)	6.3±0.94	5.9±1.7	.2830
TNM stage (%)			
T1a	3.18	0.00	.2976
T1b	1.59	0.00	
T1c	66.67	58.82	
T2a	15.87	29.41	
T2b	3.17	0.00	
T2c	3.17	0.00	
T3a	6.34	0.00	
T3b	0.00	5.88	
Treatment received			
Prostatectomy	53.85	5.88	.0148
Radiation	26.15	52.94	
Hormone therapy	4.62	5.88	
Watchful waiting	3.08	11.76	
Prostatectomy and Hormone therapy	1.54	0.00	
Radiation and Hormone therapy	10.77	23.53	

Table 2: Percent of patients returning to baseline scores at 12 months follow-up

	3 months (%)		6 months (%)		12 months (%)		Censored		Mean (Days)	
	Caucasian	AA	Caucasian	AA	Caucasian	AA	Caucasian	AA	Caucasian	AA
Generic HRQoL										
Physical function	71.93	50.00	76.27	64.29	80.30	61.11	8.96	33.33*	154	230*
Role physical	55.36	83.33	87.72	61.54*	82.81	62.50	5.97	25.00*	167	180
Role emotional	73.21	58.33	84.21	69.23	88.71	50.00*	3.08	25.00*	148	196*
Vitality	46.43	66.67	72.41	46.15	68.66	47.06	13.43	29.41	198	211
Mental health	69.64	84.62	81.03	64.29	79.10	72.22	5.97	16.67	162	175
Social function	53.57	53.85	78.95	50.00*	77.27	50.00*	12.12	33.33*	182	235
Bodily pain	54.39	30.77	65.52	57.14	73.13	38.89*	17.91	44.44*	194	250*
General health	75.44	69.23	83.33	16.7	71.64	77.78	13.43	11.11	154	195
Prostate cancer specific HRQoL										
Urinary function	40.74	61.54	56.90	61.54	56.25	52.94	25.00	27.78	222	220
Bowel function	70.91	58.33	72.41	58.33	76.56	64.71	12.50	17.65	161	217
Sexual function	40.00	30.00	35.85	40.00	37.29	50.00	50.85	46.67	244	282
Urinary bother	35.85	46.15	64.91	42.86	69.84	50.00	22.22	33.33	215	260
Bowel bother	87.27	58.33*	87.93	66.67	82.81	64.71	0.00	17.65*	126	217 *
Sexual bother	63.27	40.00	58.00	10.00*	54.24	35.71	25.42	60.00*	193	288 *

* $p < 0.005$

Table 3: Predictors time to return to baseline (Backward stepwise log-linear regression)

Model	Covariates	OR	SE	p value
Physical function	PSA score (baseline)	0.99	0.007	0.0638
	Race	.59	0.147	0.0008
	TNM stage	1.99	0.236	0.0047
	Baseline score	1.01	0.003	0.0024
Role physical	Race	0.73	0.163	0.0593
	Baseline score	1.01	0.002	0.0023
Role emotional	PSA score (baseline)	0.99	0.007	0.1128
	Race	0.68	0.149	0.0126
	TNM stage	1.88	0.237	0.0095
	Baseline score	1.03	0.002	0.1041
Vitality	Baseline score	1.52	0.238	0.0807
	TNM stage	1.01	0.004	0.0220
Mental health	Treatment (Radical Prostatectomy)	0.81	0.137	0.1286
	Baseline score	1.01	0.004	0.0774
Social function	Charlson comorbidity score	1.05	0.027	0.0853
	Race	0.59	0.161	0.0016
	Age	0.97	0.015	0.0584
	TNM stage	1.75	0.218	0.0127
	Baseline score	1.01	0.004	0.0335
Bodily pain	Race	0.68	0.163	0.0190
	Baseline score	1.01	0.003	0.0027
General health	Race	0.64	0.160	0.0064
	TNM stage	1.58	0.219	0.0379
	Baseline score	1.01	0.002	0.0267
Urinary function	Race	0.69	0.170	0.0328
	Treatment (Radical Prostatectomy)	1.54	0.156	0.001
	Baseline score	1.01	0.005	0.0076
Bowel function	PSA score (baseline)	0.98	0.008	0.0305
	Race	0.66	0.199	0.0376
	Treatment (Radical Prostatectomy)	0.70	0.170	0.0405
	TNM stage	2.01	0.265	0.0108
Sexual function	Race	0.63	0.143	0.0019
	Treatment (Radical Prostatectomy)	1.70	0.131	0.0001
	Age	0.97	0.015	0.0567
	Baseline score	1.01	0.002	<.0001
Urinary bother	Baseline score	1.01	0.003	0.0154
Bowel bother	PSA score (baseline)	0.99	0.006	0.0504
	Race	0.62	0.134	0.0007
	TNM stage	2.18	0.217	0.0006
Sexual bother	Race	0.56	0.18	0.0022
	Baseline score	1.01	0.002	0.0016

Table 4: Health Related Quality of Life scores at each point and treatmentgroups

	Baseline (mean± std)		3 months (mean± std)		6 months (mean± std)		12 months (mean± std)	
	Caucasian	AA	Caucasian	AA	Caucasian	AA	Caucasian	AA
Generic HRQoL								
Physical function	63.9±21.7	49.7± 28.4	58.9±21.6	37.5±25.1*	62.6±19.9	40.9±26.5*	62.8±20.8	47.3±25.9*
Role physical	77.3±38.9	50.0± 42.4*	53.1± 45.2	36.5±45.2	75.9±39.8	48.5±46.3*	78.0±34.4	41.7±43.5*
Role emotional	85.1± 31.7	70.6± 40.6	73.1± 39.1	58.9±43.4	82.2±35.9	66.7±47.1	90.4±25.3	55.6±43.9*
Vitality	67.5± 20.7	66.5 ± 21.3	56.4±22.4	55.8±22.1	68.4±24.7	55.9±26.9	65.3±25.6	56.3±22.3
Mental health	78.7± 15.1	74.7± 19.1	76.1± 15.1	77.7±14.4	79.9±15.5	78.8±14.1	82.8±15.4	78.6±15.2
Social function	89.0± 18.1	81.2± 23.2	71.7±27.7	71.2±23.6	86.6±22.8	66.9±28.3*	86.1±23.8	73.3±25.7*
Bodily pain	83.2± 22.8	76.8 ± 22.8	71.4±27.8	58.3±22.0	81.6±23.7	63.2±29.1*	81.7±22.1	63.5±26.9*
General health	68.3± 22.9	55.8 ± 20.2*	65.6± 23.1	55.0±17.1	67.5±24.5	57.1±19.0	66.3±24.1	57.3±20.5
Prostate cancer specific HRQoL								
Urinary function	89.3±15.2	83.1± 14.1	67.2±29.9	78.9±19.3	78.4±23.1	75.7±26.3	81.0±20.0	79.3±23.0
Bowel function	88.6±14.6	91.4± 8.5	87.1±14.5	77.3±21.2*	86.9±16.2	81.2±22.3	87.8±14.4	81.5±21.6
Sexual function	36.3±27.9	44.0± 31.3	17.8±22.3	30.1±19.1	16.1±21.9	24.3±23.2	22.4±24.6	25.9±23.6
Urinary bother	83.6±24.5	90.3± 17.5	64.3±28.1	63.5±34.8	77.9±29.0	64.7±34.3	80.9±23.3	75.0±29.9
Bowel bother	88.1±18.8	92.6± 11.7	87.7±20.7	69.2±30.9*	91.1±19.0	78.1±31.5*	88.9±20.4	76.1±34.0*
Sexual bother	55.4±39.9	68.3± 40.6	43.1±41.3	43.8±41.6	40.3±40.5	21.7±32.6	42.4±38.5	31.2±38.8
Satisfaction with care	27.6±3.6	28.3±3.5	28.7±3.7	29.1±3.1	28.4±4.8	27.7±7.3	27.7±5.2	28.9±4.1

* $p < 0.005$

Health-related quality of life and satisfaction with care among older men treated for prostate cancer with either radical prostatectomy or external beam radiation therapy

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OBJECTIVE

To analyse health-related quality of life (HRQoL) and satisfaction with care across potential curative treatments for older patients newly diagnosed with prostate cancer.

PATIENTS AND METHODS

In a prospective cohort study we recruited 115 older patients (≥65 years) newly diagnosed with prostate cancer from the urology clinics of an urban academic and a Veterans' Administration (VA) hospital. Patients completed generic (Short Form-36), prostate-specific (University of California Los Angeles Prostate Cancer Index) HRQoL, and Client Satisfaction with Care (CSQ-8) surveys before treatment with either radical prostatectomy (RP) or external beam irradiation (EBRT) and at 3, 6 and 12 months afterward. Clinical and demographic data were obtained via medical chart review. A repeated-measures analysis of variance was used to examine changes in generic and prostate cancer-specific HRQoL between treatments. Log-linear regression was used to analyse the factors associated with 12-month HRQoL scores, and Kaplan–Meier survival curves were used to compare the return to baseline values for HRQoL.

RESULTS

The RP group had a significantly higher income, education and better general health than the EBRT group. Age (odds ratio 0.5, 95% confidence interval 0.32–0.82), non-VA hospital (28.8, 2–402) and prostate-specific antigen level at diagnosis (2.8, 1.05–7.5) were associated with RP. The analysis results indicated that the RP group had higher scores for generic HRQoL subscales of physical function ($P = 0.019$), role emotional ($P = 0.037$), vitality ($P = 0.033$) and general health ($P = 0.05$) than the EBRT group. A log-linear regression model for predicting the 12-month scores showed that RP was associated with higher scores for most of the generic HRQoL and bowel function (odds ratio 1.12, $P = 0.03$), urinary bother (1.6, $P = 0.014$) and bowel bother (1.5, $P = 0.013$). Being older was associated with a lower score on bowel function (0.98, $P = 0.05$) and sexual function (0.92, $P = 0.05$). Satisfaction with care was comparable between treatment groups at baseline and at the follow-up.

CONCLUSIONS

Older patients tolerate RP well from the HRQoL perspective and thus decisions for therapy in this age cohort should not be based primarily on age.

KEYWORDS

prostate cancer, health-related quality of life, satisfaction with care, prostatectomy, external beam radiation

INTRODUCTION

Prostate cancer is the leading cancer diagnosed among older men in the USA, with a median age at diagnosis of 72 years [1]. The ageing of the population and exponential increase in the incidence of prostate cancer are important factors that will affect future morbidity and mortality from the disease [2]. Due to uncertainty in screening and treatment, debate on outcomes such as quality of life (QoL) continues [2–9]. Assessing the effects of different treatments for prostate cancer on the health-related QoL (HRQoL) of older patients has significant clinical and health policy implications. Radical prostatectomy (RP) and external beam radiation therapy (EBRT) are the most common curative treatments for older men with locally (advanced) prostate cancer. In the present prospective study we analysed the baseline characteristics associated with the treatment of older men with prostate cancer (RP or EBRT) and assessed their short-term effects on generic and prostate cancer-specific HRQoL and satisfaction with care, controlling for stage of cancer at diagnosis and comorbidity.

PATIENTS AND METHODS

A prospective cohort design was used to recruit 115 older patients (≥65 years) newly diagnosed with prostate cancer. Patients were recruited into the study after completing the informed consent and Health Insurance Portability and Accountability Act (HIPAA) forms. The study was reviewed and approved by the institutional review board. All personnel involved in the conduct of the study completed subject-protection training and met the appropriate HIPAA education requirements before engaging in this research.

To assess generic and prostate cancer-specific HRQoL and satisfaction with care at baseline, participants completed the Short Form-36, the University of California Los Angeles Prostate Cancer Index (UCLA-PCI) and Client

Satisfaction with Care (CSQ-8) surveys during enrolment or via mail within 1–2 weeks after their enrolment into the study. All three self-assessment survey instruments have been extensively studied and validated [10–12]. Participants also completed these self-administered surveys at 3, 6 and 12 months after treatment. A structured medical chart review was used to collect demographic data (age, ethnicity and health insurance) and clinical data such as histological grade of the tumour using Gleason score, TNM stage of cancer, PSA level at diagnosis, follow-up PSA level, and comorbidity. Prostate cancer treatment was classified as RP (RP as monotherapy and multimodal therapy) vs EBRT (monotherapy and multimodal therapy). The baseline Charlson comorbidity score (CHS) was computed using International Center for Disease-9 codes for all inpatient and outpatient events [13]. The CHS is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of the burden of illness [13].

Study participants were older men (≥65 years) diagnosed with prostate cancer and were recruited within 4 months of their diagnosis or before treatment. They were identified and recruited at the urology clinics of an academic medical centre and a Veterans Administration (VA) medical centre between February 2002 and July 2004. A patient was ineligible if he had visited these clinics for a second opinion only and not for continued care, was medically unstable or disoriented and/or if he was unable to communicate in English.

Initial information about the study was provided to potential participants by their urologists during clinic visits. A study research assistant then contacted those who had expressed an interest in participating in the study. Also, attendees of the weekly prostatectomy orientation class were contacted after the meeting. Those interested completed the informed consent form and HIPPA form. During study enrolment, participants were informed about the importance of continued and active participation. Of the total 115 participants enrolled into the study, 107 completed the 3-month, 105 the 6-month and 102 the 12-month follow-up surveys.

Generic and prostate-specific HRQoL subscale raw scores were converted to a scale of 0–100, a higher score indicating a better QoL. Similarly, a higher score on the CSQ-8 indicates greater patient satisfaction with care. The *t*-test and chi-square test were used to compare demographic and clinical variables between treatment groups. A backward stepwise logistic regression model was used to identify predictors of treatment. Covariates were age, CHS, TNM stage, Gleason score, PSA score, race, marital status, education and type of hospital. The mean HRQoL at baseline and at 3, 6 and 12 months was compared between the RP and EBRT groups. Backward stepwise log-linear regression was used to determine the predictors of 12-month scores on prostate-specific and generic HRQoL domains. Covariates were age, ethnicity, CHS, marital status, education, baseline score, treatment group and TNM group. The following variables were dichotomized: race (1, Caucasian; 0, African-American); marital status (1, married; 0, other); education (1, high school or less, 0, more than high school); treatment group (1, RP; 0, EBRT); and TNM group (1, T1a-T2a; 0, T3a-T3b). A repeated-measures ANOVA was used to analyse the impact of treatment on generic and cancer-specific HRQoL. As a measure of recovery after treatment, we compared 'return to baseline' for each subscale of generic and cancer-specific HRQoL. During the follow-up a participant was considered as having 'returned to baseline' for a given HRQoL domain if the difference in scores between baseline and follow-up was a clinically significant difference of ≤7 points [10,14]. We compared the proportion of patients 'returning to baseline' across treatment groups at 3, 6 and 12 months of follow-up for the generic and cancer-specific HRQoL subscales using chi-square analysis and Kaplan–Meier survival analysis.

RESULTS

A comparison of demographics, signs and symptoms by treatment group is presented in Table 1. The RP group had a higher percentage of participants who were Caucasian, college-educated, currently working full-time, married and had an annual income of ≥US $40 000. The overall mean (SD) age at diagnosis was 69.5 (4.5) years and the RP group, at 67.4 (1.5) years, was younger than the EBRT group, at 71.5 (3.5) years ($P < 0.001$). Prostate-specific signs and symptoms were comparable between the treatment groups, except for blood in the urine, pain or aches in the back, hips or legs, and more tired or worn out than usual, which were reported by higher proportion of the EBRT group. Table 1 also presents a comparison of the clinical characteristics. The CHS, PSA level at diagnosis, PSA level after treatment and TNM stage were comparable between the treatment groups. For the EBRT group, a higher percentage of participants had a Gleason score of 2–6 and 8–10.

As the baseline demographics and Gleason scores were different between treatment groups, we used a backward stepwise logistic regression to analyse the predictors of treatment (RP vs EBRT), which indicated that age (odds ratio (OR) 0.5, 95% CI 0.32–0.82), non-VA hospital (28.8, 2–402) and PSA score at diagnosis (2.8, 1.05–7.5) were associated with the type of RP treatment. None of the other covariates, e.g. race, CHS, Gleason score and TNM stage of cancer, were associated with the treatment.

A comparison of baseline generic and prostate cancer-specific HRQoL between groups is presented in Table 2. The RP group had higher baseline scores on physical function, role physical, social function and overall general health, and bodily pain was lower in the RP group. However, the groups were comparable in terms of role emotional, vitality and mental health. For cancer-specific HRQoL, the RP group reported higher scores on urinary function, bowel function and bowel bother. The EBRT group reported higher scores on sexual bother, whereas both groups had comparable sexual function and urinary bother.

A longitudinal assessment of generic HRQoL scores and progression after treatment for mean scores on the generic HRQoL is also shown in Table 2. The pattern of progression for physical function and role physical differed between treatment groups. The RP group reported an improvement after an initial decline at 3 months and had values similar to baseline by 12 months. However, the EBRT group did not show an improvement over baseline values. For the subscale of role emotional, the decrease in scores at 3 months was greater for RP patients, and the scores improved thereafter, and by 12 months were higher than their baseline values. The EBRT group showed a continued decline in role emotional and a significantly lower score on role emotional. Both treatment groups had a

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TABLE 1 Comparisons of the demographic characteristics, signs and symptoms at baseline, and the clinical characteristics and type of treatment received, for 115 men with prostate cancer

Covariates, %	RP (n = 69)	EBRT (n = 46)	P
Age, years			
65–75	100	79.6	0.004
75–85	0	20.4	
Caucasian	97.2	65.3	<0.001
African-American	2.8	34.7	
Education			
High school or less	27.8	49	0.050
College or more	72.2	51	
Marital status			
Single/widowed/divorced	8.3	38.8	0.002
Married	91.7	61.2	
Employment			
Full-time	22.2	8.1	0.066
Part-time/other	77.8	91.9	
Income level			
>$40 000	77.1	38.3	<0.001
≤$40 000	22.9	67.7	
Hospital type			
Non-VA	5.4	53.1	<0.001
VA	94.6	46.9	
Signs and symptoms (%)			
Difficulty/discomfort urinating	13.5	30.6	0.06
Having to urinate too often	43.2	58.3	0.16
Weak urinary stream	37.8	50.0	0.26
Infection of bladder or prostate	8.1	8.3	0.97
Blood in urine	0	10.4	0.04
Pain or aches in back, hips or legs	21.6	50.0	0.007
More tired or worn out than usual	16.2	35.4	0.04
Clinical characteristics and treatment			
PSA level, ng/mL			
At diagnosis			
0–4.9	36.1	31.1	0.322
5–9.9	47.2	37.8	
>10	16.7	31.1	
After treatment			
0–4.9	100.0	97.6	0.339
5–9.9	2.4	0	
>10.00	0	0	
Gleason score (total)			
2–6	56.8	72.3	0.003
7	43.2	14.9	
8–10	0	12.8	
TNM stage			
T1a	2.8	2.2	0.495
T1b	0	2.2	
T1c	72.2	62.2	
T2a	11.1	24.4	
T2b	5.6	0	
T2c	2.8	2.2	
T3a	5.6	4.4	
T3b	0	2.2	
CHS			
0	44.1	46.5	0.821
1–3	26.5	30.2	
>3	29.4	23.3	

decrease in vitality scores at 3 months and scores for the RP group improved thereafter. However, for the EBRT group the scores improved by 6 months and declined again by 12 months. For mental health, scores at the time of diagnosis were comparable between the groups. At 12 months after treatment, the RP group had a higher level of mental health than the EBRT group. For social function, bodily pain and general health the RP group reported higher scores at baseline and these remained higher through the follow-up and at 12 months than in the EBRT group. At 12 months after treatment the RP group reached baseline values for social function and general health, whereas the EBRT group reported a significant decline in social function and bodily pain. The repeated-measures ANOVA model showed that the RP group had higher scores for the generic HRQoL subscales of physical function ($P = 0.019$), role emotional ($P = 0.037$), vitality ($P = 0.033$) and general health ($P = 0.050$) than the EBRT group, controlling for baseline scores. Also, the mean changes in score across time on role physical ($P < 0.001$), vitality ($P < 0.001$), mental health ($P = 0.041$), social function ($P < 0.001$) and bodily pain ($P < 0.001$) were significantly different. The effect of treatment depended on time for the subscale of role physical, vitality and social function (all $P < 0.001$).

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The scores on the prostate cancer-specific HRQoL are also given in Table 2. Urinary function consists of five items and urinary bother of one. Bowel function consists of four items (rectal urgency, loose stools, distress with bowel movement and abdominal pain) and bowel bother of one. The UCLA-PCI measures sexual function by combining eight items, and sexual bother by one item. For the RP group the score on urinary function declined at 3 months and improved thereafter. For the EBRT group the score stayed somewhat constant over time. Although the score on bowel function declined slightly at 3 months in the RP group, by 12 months it returned to the baseline level. For the EBRT group the score at 12 months remained less than at baseline. For both treatment groups the score on sexual function declined over the 12 months, but more so in the RP group. However, although both treatment groups had a decline in the urinary bother score over the 12 months it was greater for the EBRT group. The bowel bother score at 12 months was better than baseline scores for the RP group; for the EBRT group it tended to decline over the

TABLE 2 Mean (SD) HRQoL scores at each time point and in each treatment group

	Baseline		3 months		6 months		12 months	
HRQoL	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT
Generic								
Physical function	67.7 (23.8)	54.6 (32.1)*	62.1 (19.7)	48.9 (24.9)*	69.9 (14.4)	47.6 (23.4)*	69.8 (15.4)	49.8 (24.2)*
Role physical	87.8 (35.6)	59.9 (56.6)*	46.2 (43.8)	52.7 (46.7)	81.4 (36.0)	60.0 (45.6)*	86.9 (24.2)	56.8 (44.4)*
Role emotional	88.9 (36.0)	77.3 (47.1)	75.5 (38.8)	66.7 (40.6)	93.3 (21.1)	66.7 (45.9)*	95.2 (15.7)	70.3 (41.1)*
Vitality	70.6 (16.9)	64.8 (28.5)	54.9 (20.5)	56.8 (23.9)	75.2 (19.4)	57.9 (27.6)*	74.1 (18.3)	54.4 (26.5)*
Mental health	78.9 (15.2)	77.0 (16.5)	75.5 (15.2)	76.9 (14.9)	83.0 (10.7)	76.7 (17.5)	85.4 (10.7)	78.8 (17.8)*
Social function	92.6 (13.9)	83.6 (22.1)*	69.1 (26.5)	73.1 (27.2)	90.7 (15.3)	75.3 (29.8)*	92.9 (13.8)	75.0 (28.7)*
Bodily pain	89.7 (15.9)	76.2 (25.4)*	71.8 (25.7)	66.2 (28.2)	88.8 (15.5)	68.3 (29.3)*	86.1 (19.6)	70.4 (25.9)*
General health	74.1 (18.0)	59.4 (24.0)*	71.6 (20.3)	56.8 (22.1)*	75.1 (17.7)	57.1 (25.3)*	73.5 (18.8)	56.9 (24.7)*
Prostate cancer-specific								
Urinary function	92.4 (13.9)	84.6 (15.5)*	51.7 (27.9)	83.7 (20.5)*	69.2 (28.5)	84.3 (16.8)*	77.1 (19.6)	83.0 (22.2)
Bowel function	92.9 (6.5)	86.3 (16.7)*	87.6 (15.2)	82.0 (18.2)	90.7 (13.2)	81.3 (19.8)*	92.2 (9.1)	81.5 (19.6)*
Sexual function	42.1 (24.0)	34.1 (31.5)	12.4 (16.0)	27.0 (24.9)*	12.8 (16.5)	22.1 (25.9)	21.7 (20.6)	24.4 (27.2)
Urinary bother	89.9 (18.1)	81.5 (26.1)	59.8 (26.5)	66.9 (31.8)	79.9 (29.8)	70.1 (30.7)	85.7 (18.4)	73.9 (28.4)*
Bowel bother	94.6 (10.4)	84.8 (20.7)*	86.0 (24.8)	81.1 (24.6)	94.4 (15.9)	83.1 (26.2)*	96.4 (10.4)	77.0 (29.7)*
Sexual bother	46.4 (38.4)	67.7 (38.8)*	32.4 (36.7)	54.5 (42.1)*	22.8 (31.6)	49.3 (41.6)*	32.7 (33.4)	46.1 (41.9)
Satisfaction with care								
	28.2 (3.7)	27.4 (3.5)	29.1 (3.0)	28.4 (3.2)	29.5 (2.8)	27.2 (6.8)	29.1 (5.9)	27.2 (5.7)

*P < 0.005.

12 months. For both treatment groups the score on sexual bother declined at 3 and 6 months; at 12 months the scores improved but they were not at baseline levels. Results of the repeated-measures ANOVA indicated that RP had a significant effect on the decline in score for the cancer-specific subscale of urinary function ($P < 0.001$), sexual function ($P = 0.002$) and sexual bother ($P = 0.012$), controlling for baseline values. The mean changes in score over time on urinary and sexual function (both $P < 0.001$), and urinary ($P = 0.042$) and sexual bother ($P < 0.001$) were significantly different. The effect of treatment depended on time for the subscales of sexual and urinary function (both $P < 0.001$), urinary bother ($P = 0.012$) and bowel bother ($P = 0.040$).

During the follow-up a participant was considered as having 'returned to baseline' for a given HRQoL domain if the difference in scores between baseline and follow-up was ≤7 points, which is considered to be a clinically significant difference [10,14]. Table 3 shows the comparison of the percentage of patients returning to baseline at 3, 6 and 12 months. For generic health at 12 months the RP group had a higher proportion returning to baseline on eight subscales than the EBRT group. The difference between the groups was significant for physical function, role emotional and social function. For cancer-specific HRQoL at 12 months, the EBRT group performed better for urinary and sexual function, but the RP group had a higher proportion returning to baseline on bowel and urinary function and bowel bother. As shown in Table 3, 'censored' observations were those patients who did not 'return to baseline' during their 12 months of follow-up. The comparison of survival curves for return to baseline of generic HRQoL showed no significant difference between treatment groups. For cancer-specific HRQoL, urinary and sexual function had significant difference in return to baseline values (Fig. 1a,b).

The results of backward stepwise log-linear regression model (Table 4) for analysing the predictors of 12-month HRQoL, controlling for baseline values, indicated that RP was associated with higher scores for physical function (OR 1.26), role physical (3.3), role emotional (1.9), vitality (1.5), social function (1.2) and general health (1.3). A higher CHS was associated with a lower score on role physical (OR 0.83), vitality (0.95) and general health (0.95). Caucasian race was associated with improved role physical (OR 2.5), role emotional (2.9) and lower bodily pain (1.4). Being married was associated with higher physical function (1.4) and less than high-school education with lower physical function (0.69). A higher TNM stage was associated with lower scores on role physical (OR 0.29), social function (0.64) and higher bodily pain (0.72). For cancer-specific HRQoL, RP was associated with higher scores on bowel function (OR 1.12), urinary bother (1.6) and bowel bother (1.5), indicating improved function. Being older was associated with lower scores on bowel and sexual function (0.98 and 0.92). Being married was associated with better scores on sexual bother (OR 4.2). A higher TNM stage was associated with lower scores on bowel function (OR 0.63), and urinary and bowel bother (0.33 and 0.19).

DISCUSSION

Older men with localized prostate cancer are offered many curative treatment choices and the process of deciding which treatment is complex [15,16]. Most patients who receive curative treatment require follow-up treatments of uncertain effectiveness [15–17]. In the present study we evaluated the impact of different treatments received by

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TABLE 3 The percentage of patients returning to baseline scores at 12 months of follow-up, with the mean days to the return

	3 months		6 months		12 months		Censored		Mean days	
HRQoL	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT	RP	EBRT
Generic										
Physical function	55.9	77.8	79.4	70.0	86.5	66.7*	8.1	18.4	167	172
Role physical	36.4	80.6*	78.8	86.8	83.8	75.0	5.4	12.8	184	158
Role emotional	70.6	71.4	87.9	76.3	94.4	69.8*	0	13.0*	140	170
Vitality	39.4	58.3	78.8	58.9	72.9	58.3	10.8	20.8	197	204
Mental health	66.7	75.7	90.9	67.5*	86.5	71.4	2.7	12.2	150	176
Social function	38.2	66.7*	78.8	69.2	83.8	62.5*	10.8	20.8	197	191
Bodily pain	38.2	59.5	75.8	55.0	72.9	61.2	18.9	26.5	206	205
General health	73.5	75.7	73.5	75.0	78.4	69.4	13.5	12.2	153	168
Prostate cancer specific										
Urinary function	15.1	71.4*	38.2	73.7*	43.3	64.5*	43.2	13.0*	274	181*
Bowel function	70.6	64.7	76.5	64.9	81.1	68.9	8.1	17.8	150	192
Sexual function	12.1	67.9*	15.1	58.1*	16.7	60.5*	80.6	23.1*	320	191*
Urinary bother	27.3	47.1	67.6	52.6	70.3	60.0	24.3	26.7	221	232
Bowel bother	79.4	82.4	88.2	81.1	91.9	68.9*	0	6.7	133	156
Sexual bother	56.2	64.3	48.4	53.3	48.6	51.3	31.4	32.5	210	211

*P < 0.005.

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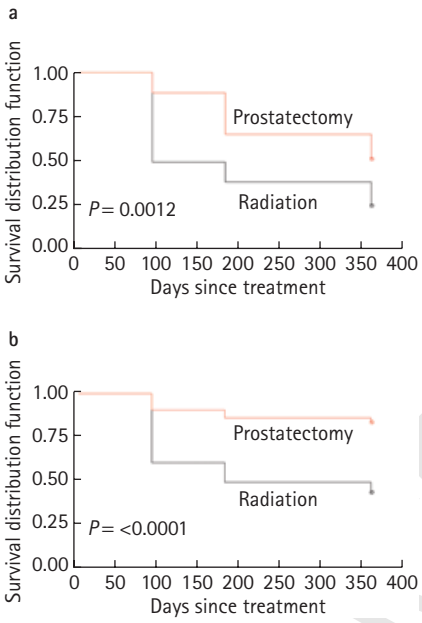
*FIG. 1. Return to baseline at 12 months for: **a,** urinary function and **b,** sexual function.*

COLOUR FIG.



older men with prostate cancer on outcomes such as HRQoL and satisfaction with care. RP for early-stage prostate cancer had comparable outcomes in terms of generic and prostate-specific HRQoL. The main findings of the study were: (i) At the 12-month follow-up, the RP group had significantly better generic HRQoL scores than the EBRT group; (ii) there were significant improvements in prostate-specific HRQoL domains, e.g. bowel function and bother and urinary bother at 12 months in the RP group; (iii) there was lower urinary and sexual function, and more sexual bother at 12 months in the RP group; (iv) the TNM stage of cancer and type of hospital (non-VA) was associated with the observed treatment pattern; and (v) there was no significant difference in satisfaction with care between the RP and EBRT group.

HRQoL plays an important and integral part of treatment decisions for prostate cancer [5,16,17]. Older men with early stages of cancer often live long after diagnosis and treatment, and desire to maximize their QoL [4,8,9,16,17]. While some studies showed that treatments for a given stage of prostate cancer vary by age [2,3,15] others have addressed the specific effect of treatment on HRQoL [6,8,18–37]. RP treatment is beneficial for patients with an estimated life-expectancy of >15 years [17,20]. Age has strong influences on treatment pattern; younger men prefer RP, middle-aged men prefer radiation therapy and older men prefer either no treatment or hormone therapy [1–8]. Since 1991, RP has been common for localized and regional stages of disease. Many studies have addressed the effect of treatments for prostate cancer on HRQoL outcomes, but very few have focused on outcomes in older men diagnosed with early-stage disease. The function before treatment and primary treatment method were strongly associated with a decline in organ-system dysfunction and the time course of dysfunction [19,22,28,36]. In a cross-sectional study, Dahn *et al.* [35] showed that the level of physical activity was positively correlated with sexual function in patients with localized prostate cancer who had EBRT. Litwin *et al.* [29] reported a longitudinal study of 438 men diagnosed with early-stage prostate cancer and treated with either pelvic irradiation or RP, assessing the impact of these on sexual function and sexual bother. There was a comparable improvement in sexual function during the first year for both treatments but sexual function declined in the second year for the pelvic irradiation group, but not for the RP group. A retrospective study comparing QoL in 203 patients treated with RP and 257 with EBRT determined that patients who received RP more often had problems with urinary incontinence [30]. A long-term assessment of HRQoL of men receiving EBRT and brachytherapy showed that their prostate-specific HRQoL scores continued to decline, whereas RP patients remained relatively stable or improved slowly [23,24,38]. A prospective study of 72 Japanese men with prostate cancer and receiving RP showed that generic HRQoL had recovered by

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6 months. A nerve-sparing RP gave better recovery of sexual function and urinary incontinence than non-nerve sparing RP [37].

A study using the Cancer of the Prostate Strategic Urologic Research Endeavor database showed that among patients receiving RP, younger men were more likely to return to baseline values for continence, potency and physical health. The preoperative tumour characteristics did not appear to be associated with regaining baseline values in any HRQoL domains [39]. Alibhai *et al.* [8] used a decision-analytical Markov model to show that older men with moderately or poorly differentiated localized prostate cancer and few comorbidities might benefit from curative therapies in terms of improved life-expectancy and quality-adjusted life-years. A long-term study to compare the HRQoL of men treated with RP or EBRT found that at 5 years after treatment decreases in urinary, bowel and sexual function persisted for both treatment groups. The most dramatic decline in sexual function was in the EBRT group at 2–5 years, leading to a comparable score with the RP group [38].

The limitations of the present study are: (i) because there was no randomization the results might not be representative of all older patients receiving either RP or EBRT, and there is potential for inherited treatment bias; (ii) the follow-up was short (12 months); (iii) the sample was limited to two large healthcare systems and may not be representative of the general elderly population.

In conclusion, as screening for prostate cancer becomes more widespread more elderly men will be diagnosed at an earlier stage [1–3]. Age has been a significant factor in clinical decision-making for treating patients with prostate cancer; older men often have a wide variation of comorbid conditions, functional limitations and generic HRQoL that may affect their treatment pattern and outcomes. Thus, managing prostate cancer in this group requires a comprehensive assessment and multidisciplinary approach to maximize the HRQoL. Little information is available on the treatment-decision process in the older patients and how these decisions affect the HRQoL outcomes. The present results indicate that older patients appear to have a better tolerance for RP. The present study is a first step in analysing the complex interplay of the characteristics of patient and provider in the decision process and its effect on HRQoL among older patients. Further research on the factors associated with long-term HRQoL of older patients from diverse hospital and treatment settings is critical for the effective management of prostate cancer.

TABLE 4
Predictors of HRQoL at 12 months, by backward stepwise log-linear regression

Model	Covariates	OR (SEM)	P
Physical function	Treatment (RP)	1.26 (0.30)	<0.001
	Married	1.42 (0.19)	0.053
	Education	0.69 (0.17)	0.001
	Baseline score	1.02 (0.003)	<0.001
Role physical	CHS	0.83 (0.07)	0.018
	Race	2.50 (0.39)	0.024
	Treatment (RP)	3.30 (0.32)	<0.001
	TNM stage	0.29 (0.55)	0.032
	Baseline score	1.01 (0.004)	0.001
Role emotional	Race	2.94 (0.45)	0.020
	Treatment (RP)	1.98 (0.35)	0.056
	Baseline score	1.01 (0.006)	0.091
Vitality	CHS	0.95 (0.02)	0.040
	Treatment (RP)	1.46 (0.09)	<0.001
	Baseline score	1.01 (0.002)	<0.001
Mental health	Baseline score	1.01 (0.002)	0.016
Social function	Treatment (RP)	1.18 (0.09)	0.049
	TNM stage	0.64 (0.15)	0.006
	Baseline score	1.01 (0.002)	<0.001
Bodily pain	Race	1.40 (0.10)	<0.001
	TNM stage	0.72 (0.13)	0.017
	Baseline score	1.01 (0.001)	<0.001
General health	CHS	0.95 (0.03)	0.042
	Treatment (RP)	1.30 (0.13)	0.040
	Age	1.03 (0.016)	0.052
	Baseline score	1.02 (0.003)	<0.001
Bowel function	Treatment (RP)	1.14 (0.05)	0.027
	Age	0.98 (0.007)	0.055
	TNM stage	0.63 (0.12)	<0.001
Sexual function	Age	0.92 (0.04)	0.061
	Baseline score	1.03 (0.006)	<0.001
Urinary bother	Treatment (RP)	1.57 (0.18)	0.014
	Education	1.45 (0.14)	0.013
	TNM stage	0.33 (0.25)	<0.001
	Baseline score	1.01 (0.003)	0.003
Bowel bother	Treatment	1.50 (0.16)	0.013
	TNM stage	0.19 (0.30)	<0.001
Sexual bother	Married	4.20 (0.55)	0.011
	Baseline score	1.02 (0.006)	0.001

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CONFLICT OF INTEREST

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Abbreviations: **RP**, radical prostatectomy; **EBRT**, external beam radiation therapy; **(HR)QoL**, (health-related) quality of life; **HIPAA**, Health Insurance Portability and Accountability Act; **UCLA–PCI**, University of California Los Angeles Prostate Cancer Index; **CSQ–8**, Client Satisfaction with Care; **CHS**, Charlson comorbidity score; **VA**, Veterans Administration.

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HEALTH RELATED QUALITY OF LIFE AND DIRECT MEDICAL CARE COST IN NEWLY DIAGNOSED YOUNGER MEN WITH PROSTATE CANCER

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ABSTRACT

Purpose: We evaluated health related quality of life (HRQOL) and the direct medical care cost (DMC) in young men receiving radical prostatectomy.

Materials and Methods: In this prospective cohort study, 40 newly diagnosed patients with prostate cancer (PCa) who were younger than 65 years were matched with 40 cancer-free men. Participants completed the Medical Outcome Study Short Form and UCLA-PCa Index surveys prior to treatment, and at 3, 6, 12 and 24-month followup. Cost data were obtained from a hospital based administrative database and clinical data were obtained via structured medical chart review. Demographics and HRQOL were compared using the t, Fisher exact and chi-square tests. The Wilcoxon and log-T tests were used to compare DMC. Multivariate regression models were used to assess the incremental cost of PCa and predictors of 24-month prostate specific HRQOL.

Results: Patients with PCa had a mean annual DMC of $4,160 for the treatment year with a mean length of stay of 3.5 days. They had 3-fold higher DMC than controls. At 12 months, generic HRQOL values were similar to baseline values. Sexual function showed trends toward improvement 6 months after surgery. Urinary function improved significantly by 6 months, although it decreased thereafter. Bowel function and bother returned to baseline values by 3 months. On multivariate regression marital status was a significant predictor of 5 domains of prostate specific HRQOL at 24 months.

Conclusions: Patients with PCa reported weaker sexual function, urinary function and sexual bother at 2 years after treatment compared with their baseline values. There exists an opportunity for improving prostate specific HRQOL in men with early stage PCa.

KEY WORDS: prostate, prostatic neoplasms, quality of life, health care costs

Health related quality of life (HRQOL) and the cost of care are important issues in prostate cancer (PCa) care. Patients with PCa have several treatment options, such as radical prostatectomy, radiation (external beam radiation and interstitial brachytherapy), hormonal therapy and watchful waiting. These treatments affect patient quality and quantity of life. With the increasing prevalence of PCa in younger men, the economic burden of PCa is substantial and growing.[1,2] Potentially curative procedures are normally offered to younger men with early stage cancer. Due to uncertainty in the effectiveness of screening and treatments for PCa, and variable natural history, debate on resulting HRQOL continues.[1–3] Many young men live for years after diagnosis and wish to maximize their HRQOL. An assessment of the effects of treatment choices on short-term and long-term HRQOL, and cost of care will facilitate effective clinical and policy decisions. We analyzed HRQOL and the direct medical care cost (DMC) in young men with newly diagnosed PCa who received radical prostatectomy.

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METHODS

Subjects. For this prospective observational cohort study, we recruited 40 men younger than 65 years with newly diagnosed PCa from the urology clinic at an academic urban medical school. Matched controls were identified from the same institution. The institutional review board approved the study and all subjects provided informed consent and Health Insurance Portability and Accountability Act forms.

Participants and recruitment. Young black or white American men with newly diagnosed PCa between 2000 and 2001 were identified, recruited prior to treatment and followed prospectively for 2 years. Patients unwilling to participate, unable to communicate in English and/or who visited the urology clinic for a second opinion only were excluded. A control group of men without cancer, matched by age and ethnicity, was identified using the Pennsylvania Integrated Clinical Administrative and Research Database (PICARD) and recruited. Upon the completion of written consent, and Health Insurance Portability and Accountability Act forms, participants were enrolled into the study.

Data collection. Health resource use and DMC data for 4 years (1 year before diagnosis, 1 year during treatment and 2 years after treatment) were obtained retrospectively from PICARD. Medical care costs are defined as reimbursements for specific services by any part of the health care organization. DMC consists of 1) hospital costs, 2) physician, professional and nurse payments, 3) diagnostic and therapeutic

procedure costs, and 4) outpatient and emergency room costs. Clinical data, such as diagnosis date, treatment (prostatectomy, radiation, brachytherapy or hormone therapy), histological tumor grade, other illnesses, Gleason score, TNM cancer stage, prostate specific antigen (PSA) level and demographics (insurance status, ethnicity and age) were obtained retrospectively via structured medical chart review. The annual Charlson comorbidity index (CHS)[4] was calculated using International Classification of Diseases-9 codes for all inpatient and outpatient events. These data were obtained from PICARD.

Measures. Cases completed generic and prostate specific HRQOL questionnaires at baseline, and at 3, 6 12 and 24-month followup. Controls completed similar questionnaires at baseline only. Generic HRQOL was measured using the Medical Outcome Study Short Form.[5] This reliable and validated instrument was designed for use in clinical practice (self-administered or by interviewer), research and general population surveys, and it assesses 8 health concepts, namely physical limitation due to health, limitations on social activities caused by physical or emotional problems, role limitations due to physical and emotional problems, bodily pain, general mental health, vitality and general health perceptions. The range of possible score for each subscale is 0% to 100% and a higher score indicates better HRQOL.[5] The UCLA PCa Index (PCI) is a comprehensive, validated, self-administered 20-item questionnaire that quantifies prostate specific HRQOL in 6 domains, namely urinary function (UF), urinary bother (UB), sexual function (SF), sexual bother (SB), bowel function (BF) and bowel bother (BB).[6]

Statistical analysis. The t and chi-square tests were used to compare demographic and clinical variables. Mean DMC and HRQOL scores were compared between cases and controls. A change of 5 to 10 points in the scale score was considered clinically significant.[5] Multivariate log-linear regression was used to calculate the incremental cost of PCa. Independent variables were age, ethnicity and CHS. Multivariate backward elimination log-linear regression was used to determine the predictors of 24-month prostate specific and generic HRQOL domains. Covariates were age, race (1 = white and 0 = black), income (1 = $40,000 or less and 0 = greater than $40,000), CHS, marital status (1 = married and 0 = other), education (1 = high school or less and 0 = greater than high school) baseline score, treatment group (1 = radical prostatectomy alone and 0 = prostatectomy plus radiation or hormone therapy) and TNM group (1 = T1a to T2a and 0 = T3a to T3b).

RESULTS

Table 1 lists demographics, signs and symptoms in the study population. The majority of participants were white, college educated, currently working full time, married and with an annual income level of $40,000 or more. The mean age of cases was 57.7 years and that of controls was 59.3 years. Demographics were comparable between the groups. Mean CHS was higher in cases, indicating a higher prevalence of coexisting morbidity. A higher proportion of cases had difficulties/discomfort with urination and a weak urinary stream. A significantly higher proportion of controls experienced pain in the back, hips or legs. There were no significant differences with having to urinate too often, bladder infection, blood in the urine and tiredness.

Table 2 lists the clinical characteristics of cases at diagnosis and the treatment received. Clinical and pathological stages ranged from T1N0M0 (clinically unapparent tumor not palpable or visible by imaging or T1, no regional lymph node metastasis or N0 and no distant metastasis or M0) to T3bN0M0 (tumor extending through the prostate capsule or T3, no regional lymph node metastasis or N0 and no distant metastasis or M0). Tumors were moderately differentiated with a mean Gleason score ± SD of 6.42 ± 0.5. Mean PSA was 6.27 ± 3.65 ng/ml. Patients mostly received radical prostatectomy alone as primary treatment with a mean length of stay of 3.31 days.

Table 3 shows the DMC comparison. For the treatment phase we found significant difference in mean inpatient, outpatient and total medical care cost. However, the groups showed no differences in medical care cost in prediagnosis and posttreatment phases, suggesting that patients with PCa achieved normalcy in resource use after treatment. Incremental cost analysis for PCa indicated that the cost of care in patients with PCa was 3.8 times greater than that in controls ($p = 0.002$).

Baseline HRQOL. Table 4 shows a comparison of baseline generic and prostate specific HRQOL between the groups. The groups were not different with respect to role physical, role emotional, vitality, mental health and social function.

TABLE 1. *Baseline demographic characteristics, signs and symptoms*

Covariates	PCa	Controls	p Value
Mean age ± SD (range)	57.7 ± 5.2 (44–63)	59.3 ± 3.4 (54–63)	0.1347
Mean CHS ± SD (range)	1.76 ± 2.9 (0–8)	0.79 ± 1.6 (0–8)	0.0956
% Race:			
White	91.4	91.2	0.9704
Black	8.6	8.8	
% Education:			
High school or less	26.47	17.65	0.3803
College or more	73.53	82.35	
% Marital status:			
Single/widowed/divorced	11.76	23.53	0.2032
Married	88.24	76.47	
% Employment:			
Full time	76.47	48.48	0.0179
Part time/other	23.53	51.52	
% Income ($):			
Greater than 40,000	84.85	75.86	0.3715
40,000 or Less	15.15	24.14	
% Signs + symptoms:			
Difficulty or discomfort urinating	26.5	6	0.044
Having to urinate too often	27.3	20.6	0.57
Weak urinary stream	29.4	5.9	0.023
Bladder or prostate infection	3	2.94	0.51
Blood in urine	0	2.94	0.5
Pain or aches in back, hips or legs	11.76	50	0.0003
More tired or worn out than usual	18.2	20.6	0.23

Total of 40 patients per group.

TABLE 2. *Clinical characteristics and treatment in patients with PCa*

Mean ng/ml PSA at diagnosis ± SD (range)	6.27 ± 3.65 (0.7–17.4)
Mean total Gleason score ± SD (range)	6.42 ± 0.5 (6.0–7.0)
% TNM stage:	
T1a	15
T1b	30
T1c	7.5
T2a	2.5
T3a	37.5
T3b	7.5
% Treatment:	
Prostatectomy alone	93.75
Prostatectomy + radiation therapy	13.33
Prostatectomy + hormonal therapy	6.45

Controls were physically less functional, had greater bodily pain and expressed lower general health than cases. They were also sexually less functional and experienced higher BB and SB.

Generic HRQOL. Figure 1 shows posttreatment progression for case mean scores on bodily pain, social function, mental health and general health. Mental health score remained mostly constant between baseline and 24 months, and it was comparable to that in controls 24 months after treatment. After initial worsening bodily pain returned to baseline by 24 months, whereas social function was higher than its baseline level. By 24 months, general health also returned to the baseline level. Figure 2 shows posttreatment progression for physical role and function, role emotional and vitality. After decreasing at 3 months, scores on these 4 domains improved by 24 months. Emotional role showed the highest improvement compared with the baseline level with a clinically significant change of 13 points. All other domains of generic HRQOL were at least equal to baseline values by 24 months.

UF and UB. The score on the UF scale at 24 months was 16.7 points lower than the baseline value (fig. 3). However, it should be noted that by 24 months UF had improved significantly after a steep decrease of 38.4 points at 3 months. UB at 24 months was 11 points lower than at baseline (fig. 4). UF consists of 5 items and UB consists of 1. At the item level, after 1 posttreatment year, the majority of patients reported that UF had not been a problem or had been a very small problem. This number had not changed much by 24 months. At 12 months, 97% of patients had total urinary control or occasional dribbling and at 24 months 96% reported these results.

BF and BB. Three months after treatment, BF and BB had returned to the baseline level and they remained constant or improved at 24 months (figs. 3 and 4). No clinically significant change was observed in these domains. BF consists of 4 items (rectal urgency, loose stools, distress with bowel movement and abdomen pain) and BB has 1. At baseline, about 90% of participants reported no problems with these items and this number stayed constant or improved at 24 months.

SF and SB. The SF scale score decreased at 3 months and improved thereafter (fig. 3), whereas SB began to improve at 24 months. However, the 2 scales showed a clinically and statistically significant decrease at 24 months compared with baseline. PCI measures SF by combining 8 items and SB by 1 item. At baseline, 74% of patients had good/very good ability to function sexually and 28% reported so at 24 months.

TABLE 3. *Direct medical care costs*

	Before Diagnosis		Treatment		After Treatment	
	Cases	Controls	Cases	Controls	Cases	Controls
Inpt ($):						
Mean ± SD	122.4 ± 679.0	0	3,384.4 ± 2,772.3*	0.04 ± 0.2	0	0
Median	0.0	0	3,739.8	0	0	0
Range	0–3,964	0	0–9,904	0	0	0
Mean length of stay ± SD (days)			3.31 ± 1.01			
Outpt ($):						
Mean ± SD	102.4 ± 353.6	179.7 ± 327.7	776.4 ± 1,861.6*	142.5 ± 377.5	180.4 ± 321.1	149.8 ± 239.6
Median	1.0	48.6	0	1.0	56.5	8.0
Range	0–1,551	1–1,367	0–7,304	0–1,684	1–1,780	1–893
Total ($):						
Mean ± SD	224.8 ± 749.1	179.7 ± 327.7	4,160.8 ± 2,395.1*	142.5 ± 377.5	180.4 ± 321.1	149.8 ± 239.6
Median	1.0	48.0	3976.7	1.0	56.5	8.0
Range	0–1,551	0–1,376	0–9,904	0–1,684	0–1,780	0–893

Total of 40 patients per group.
* Significant at 0.05 level.

TABLE 4. *Baseline HRQOL*

HRQOL Subscale	Mean PCa ± SD (range)	Mean Controls ± SD (range)	p Value
Generic:			
Physical function	72.6 ± 13.7 (25.0–80)	61.0 ± 21.7 (5.0–80)	0.0107
Role physical	86.8 ± 26.9 (0.0–100)	83.3 ± 29.1 (0.0–100)	0.6183
Role emotional	77.1 ± 38.3 (0.0–100)	85.9 ± 30.1 (0.0–100)	0.3072
Vitality	71.7 ± 17.9 (31.3–100)	70.9 ± 22.3 (6.3–100)	0.8814
Mental health	76.8 ± 16.4 (30.0–95)	81.9 ± 15.9 (25.0–100)	0.1931
Social function	85.7 ± 29.9 (25.0–100)	84.9 ± 29.8 (0.0–100)	0.9066
Bodily pain	91.5 ± 16.7 (32.5–100)	76.9 ± 24.0 (0.0–100)	0.0054
General health	74.3 ± 21.6 (25.0–100)	64.4 ± 24.6 (0.0–100)	0.0838
PCa-specific:			
UF	93.9 ± 13.4 (51.6–100)	96.3 ± 11.4 (53.2–100)	0.4311
BF	92.3 ± 9.4 (61.8–100)	88.3 ± 17.4 (25.0–100)	0.2381
SF	71.5 ± 21.9 (19.8–97)	48.7 ± 31.1 (0.0–100)	0.0009
UB	94.1 ± 13.8 (50.0–100)	94.9 ± 14.8 (50.0–100)	0.8331
BB	96.9 ± 8.3 (75.0–100)	86.0 ± 28.9 (0.0–100)	0.0411
SB	89.1 ± 26.9 (0.0–100)	69.4 ± 35.8 (0.0–100)	0.0160

Total of 40 patients per group.

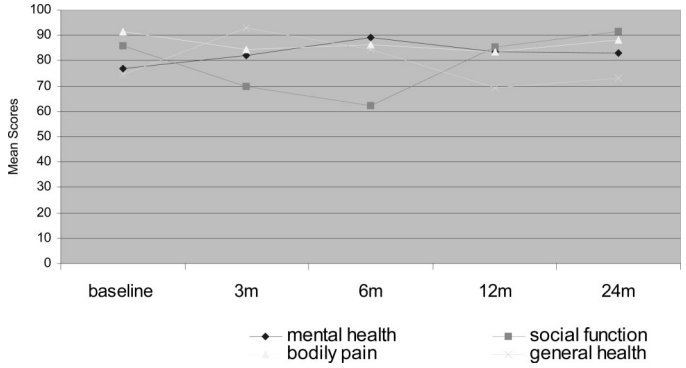

FIG. 1. Generic QOL progression. *m*, months

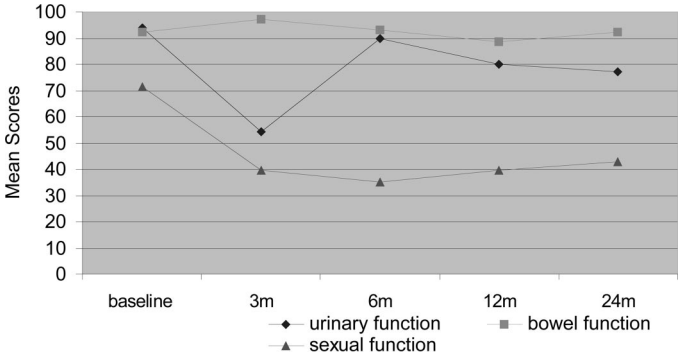

FIG. 3. HRQOL progression. *m*, months

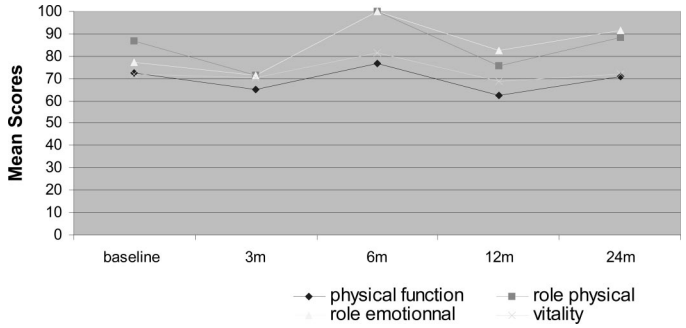

FIG. 2. Generic QOL progression. *m*, months

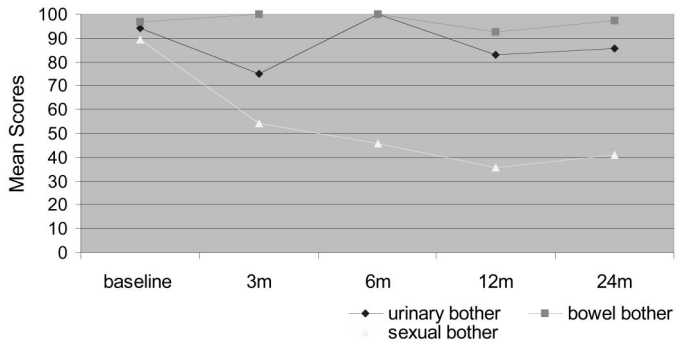

FIG. 4. HRQOL progression. *m*, months

At baseline 73% of patients were sexually active and 35% continued to be active at 24 months. Compared with baseline, at 24 months the majority of patients reported poor ability to achieve erection, poor quality of erection and poor level of sexual desire. At baseline 79% of patients reported that they had good/very good ability to achieve orgasm and by 24 months 53% reported these results.

Marital status and CHS were significant predictors of 24-month scores on social function, bodily pain and general health (table 5). The other 5 domains of generic HRQOL did not have any significant predictors. Those receiving radical prostatectomy alone (vs adjuvant therapy) had better score on 24-month bodily pain, indicating lower pain. Higher TNM stage was associated with poorer general health at 24 months.

The result of backward elimination, multivariate log-linear regression indicated that marital status was a significant predictor of the 24-month score on 5 domains of prostate specific HRQOL (table 6). Patients receiving radical prostatectomy alone vs adjuvant therapy had a better score on 24-month UF, BF and UB.

DISCUSSION

The preliminary findings of this study are that 1) younger patients with early stage PCa who undergo radical prostatectomy as primary treatment returned to baseline generic HRQOL by 6 months, 2) normalcy in cost and health resource use was achieved by the end of year 1 of treatment, 3) significant improvements in prostate specific HRQOL domains, such as BF, BB and UB, were observed, 4) decreased UF, SF and SB were observed at 24 months and 5) marital status was a significant predictor of the 24-month score on 5 domains of prostate specific HRQOL.

Several studies have addressed the issues surrounding HRQOL in patients with PCa using retrospective and prospective cohort study designs, and valid instruments, such as the Medical Outcome Study Short Form, UCLA-PCI, Expanded Prostate Cancer Index, European Organization for the Research and Treatment of Cancer-Core Quality of Life Questionnaire and Functional Assessment of Cancer Therapy-Prostate.[3–5,7–20] Studies have shown treatment derived differences in short-term and long-term HRQOL.[8–15,18–20] In the immediate short term after treatment, HRQOL decreased significantly in patients with localized PCa receiving prostatectomy.[8] Using the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) longitudinal database, Litwin et al reported that patients with PCa who underwent surgery showed improved urinary function during year 1 that remained fairly constant by year 2.[18] Although age, ethnicity and comorbidity were not associated with UF or UB, being married was associated. In another study using the CaPSURE database, Hu et al observed that younger patients receiving prostatectomy were more likely to regain baseline continence, potency and physical health.[19] Clinical stage, PSA and Gleason sum were not predictors of returning to baseline HRQOL. In a recent study of Potosky et al, men receiving prostatectomy continued to show decreased SF and UF 5 years after diagnosis.[20] Demographic, social and psychosocial factors were identified as important predictors of HRQOL.[5,11,18] In a study of a population based, longitudinal cohort with up to 24 months of followup, Stanford et al concluded that radical prostatectomy was associated with significant erectile dysfunction and some decrease in UF.[14] Steineck et al evaluated symptoms and HRQOL in men randomized to radical prostatectomy or watchful waiting.[17] Erectile dysfunction and urinary leakage were more common in the prostatectomy group. BF, the prevalence of anxiety, well-being and subjective HRQOL were similar in the 2 groups. At 12 months after treatment, men receiving radical prostatectomy experienced a significant decrease in UF, SF and SB.[10] Lubeck et al used the CaPSURE database to report that patients with prostatectomy had improved HRQOL at 1 year compared with just after surgery.[15] Using the Surveillance, Epidemiology and End Results database, Penson et al reported that UF, SF, UB and SB were independently associated with worse general HRQOL.[16] Our results confirm the

TABLE 5. *Predictors of 24-month generic QOL subscales*

Covariates	Social Function			Bodily Pain			General Health		
	OR	95% CI	p Value	OR	95% CI	p Value	OR	95% CI	p Value
Intercept	48.1	23.1–99.5	<0.0001	134.3	23.8–749	<0.0001	14.9	11.1–19.9	<0.0001
Age	0.99	0.98–1.0	0.08	0.98	0.96–1.0	0.050	—	—	—
Married	2.03	1.5–2.7	0.0001	1.9	1.3–2.8	0.005	1.61	1.2–2.1	0.0010
Education	—	—	—	1.2	0.97–1.4	0.09	—	—	—
Income	0.79	0.65–0.97	0.020	0.65	0.46–0.92	0.020	—	—	—
CHS	0.97	0.95–0.99	0.007	0.95	0.93–0.98	0.004	0.95	0.93–0.97	<0.0001
TNM stage	0.91	0.79–1.01	0.080	0.86	0.73–1.02	0.08	0.75	0.66–0.86	0.0003
Treatment	—	—	—	1.6	1.16–2.3	0.008	—	—	—
Baseline social function	1.006	1.00–1.01	0.0003	—	—	—	—	—	—
Baseline general health	—	—	—	—	—	—	1.02	1.01–1.09	<0.0001
R^2	0.94			0.87			0.93		

TABLE 6. *Predictors of 24-month HRQOL subscales*

Covariates	OR	95% CI	p Value
SF:			
Intercept	0.005	0–2.9	0.0980
Age	1.07	1.01–1.15	0.0900
Married	20.4	4.2–98	0.0001
Education	—	—	—
Race	—	—	—
Income	3.4	0.93–12.7	0.0600
CHS	0.85	0.76–0.95	0.0082
TNM stage	0.58	0.36–1.11	0.0900
Treatment	—	—	—
Baseline SF	1.03	1.01–1.05	0.0005
Baseline SB	—	—	—
R^2	0.74		
UF:			
Intercept	1.43	0.69–2.9	0.3100
Married	12.43	8.8–17.5	<0.0001
Education	1.33	1.08–1.6	0.0110
Race	1.43	0.96–2.1	0.0780
TNM stage	1.35	1.5–1.6	0.0014
Treatment	2.74	1.6–3.89	<0.0001
R^2	0.94		
BF:			
Intercept	60.34	53–113	<0.0001
Married	1.24	1.1–1.4	0.0002
CHS	0.99	0.99–1.0	0.0400
Treatment	1.3	1.2–1.4	<0.0001
R^2	0.75		
SB:			
Intercept	0.005	0–0.72	0.0460
Married	33.0	12.1–89	0.0390
Education	0.03	0.002–0.34	0.0080
Treatment	17.9	0.66–48.7	0.0800
Baseline SB	1.02	0.99–1.05	0.0900
R^2	0.53		
UB:			
Intercept	0.54	0.29–1.03	0.0620
Married	92.7	59–146	<0.0001
CHS	0.97	0.94–1.0	0.0800
Treatment	1.83	1.2–2.9	0.0100
R^2	0.96		

general longitudinal trend in generic and prostate specific HRQOL reported in these studies. We observed that, while most generic and prostate specific HRQOL domains decreased 3 months after treatment, except for SF, UF, SB and UB, all other domains showed an improving trend by 12 months. Saigal and Litwin reported that wide ranges of cost estimates were associated with PCa across different stages of cancer and they varied significantly by treatment type.[1]

There are several limitations to our study. 1) Small sample size and homogeneity due to recruitment from a single medical center may limit generalizability. However, our study results are in accordance with the trend noted in earlier studies. 2) There was a potential bias for inconsistency between reported (PICARD) services and actual services provided. 3) Indirect costs (caregivers, loss of productivity, early morality, etc) of PCa not used in our analysis could affect cost estimates. 4) The controls were matched by age and ethnicity only. Thus, the observed differences in HRQOL between cases and controls at baseline could be attributable to variations not captured by the matching process. 5) The controls were not followed longitudinally. Thus, we were not able to observe the changes in their comorbidity and HRQOL. Our future research addresses some of these limitations.

CONCLUSIONS

The widespread use of PSA testing has resulted in dramatic increases in the number of men diagnosed at a younger age and at an earlier stage of disease.[1–3] Radical prostatectomy may benefit patients with localized PCa. However, effects on HRQOL continue to be a puzzle. Our study suggests that in the short term (3 months after treatment), except for mental health, the other 7 domains of generic health decreased, as did other measures of prostate specific HRQOL, except BB and BF. However, in the long term (24 months), most generic HRQOL related domains were equal to or higher than the baseline level. Except for BF and BB, the other domains of prostate specific HRQOL (SF, UF, SB and UB) remained significantly lower than their baseline values. Although our control group was cancer-free, and matched by age and ethnicity, this group had lower mean CHS, indicating better health. However, cases had better generic and prostate specific HRQOL at baseline. Thus, the cross-sectional approach of comparing cases and controls to determine treatment effects can lead to a more biased conclusion than that from a longitudinal cohort approach. There exists a tremendous opportunity to enhance posttreatment HRQOL in younger men diagnosed with early stage PCa. Multiple factors (demographic, environmental, clinical, social and economic) influence HRQOL and must be addressed by adopting a multidisciplinary approach during the diagnosis, treatment and posttreatment phase.

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EDITORIAL COMMENT

Disease specific survival is typically the primary outcome analyzed in research on radical prostatectomy. However, the prevalence of PCa diagnosed and treated in younger men is increasing and the potential impacts on costs and HRQOL are significant. These authors designed a prospective case-control study using validated instruments to examine the impact of radical prostatectomy on DMC and HRQOL in a younger cohort. Control subjects were not followed longitudinally and the natural deterioration in HRQOL that occurs in everyone with time could not be captured for comparison. The authors recognize this design limitation. Although obtained from a small cohort, the findings may have significant implications for public policy decisions related to health care costs and the ability to counsel individuals about potential outcomes related to HRQOL. Future research examining larger populations will increase the generalizability of these results.

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Original article

Medical care cost of patients with prostate cancer

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Abstract

Objective: To analyze variations in direct medical care cost of patients with prostate across two racial groups after controlling for age, disease stage, and comorbidity.

Methods: In this retrospective cohort control study, we randomly selected 120 newly diagnosed prostate cancer patients (60 African Americans and 60 White) from the administrative database of a large urban academic hospital. Medical care costs data and clinical data were obtained. The control group consisted of 240 men without cancer, and matched by age and race. Demographics, clinical variables and treatment patterns were compared across race using *t*-test and χ^2. Mean medical care costs for prostate cancer patients were compared by race, using bootstrap and log *t*-test. Regression models were used to estimate the incremental cost of prostate cancer, and to analyze the association between race and direct medical care cost.

Results: Whites were more likely to receive radical prostatectomy, whereas African Americans were more likely to receive radiation therapy. The incremental cost of prostate cancer was 1.30 times higher than controls. Charlson comorbidity was a significant predictor of type of treatment received and cost. Race was not associated with total direct medical care cost after controlling for age, Charlson comorbidity and stage of cancer at diagnosis.

Conclusions: Charlson Comorbidity score was a predictor of type of treatment and direct medical care cost. While analyzing the association between race and cost of care, potential bias-inducing factors such as clinical characteristics at diagnosis and provider characteristics (physician and hospital) must be addressed.

Keywords: Prostate cancer; Direct medical care cost; Incremental cost; Race

1. Introduction

Cost and health status utility are relevant to many health conditions. The multiple treatment strategies for prostate cancer provide a unique arena for examining associated costs and utilization of care. Prostate cancer is the leading cancer diagnosed among men in the United States and accounts for a significant proportion of health care cost [1–9]. The American Cancer Society reported that in 2003 approximately 230,110 men were diagnosed with prostate cancer and 29,900 might have died of it [1,3,4]. The economic burden of this slow, progressive disease is substantial and growing [5–9]. The annual cost of treating prostate cancer in the U.S. amounts to several billion dollars. As majority of the men diagnosed with prostate cancer are elderly, Medicare shoulders most of the cost burden [3,7,9]. Despite the cost, uncertainty exists regarding the effectiveness of various treatments for prostate cancer [7–13].

Age, ethnicity and a family history of prostate cancer are the only well established risk factors for prostate cancer [1–8,11]. The incidence of prostate cancer in African American men is 1.6 times greater than that in White men [1,3,4]. Among African American men, prostate cancer is the leading type of newly diagnosed cancer (39%), and second leading cause of death (16.3%) [4].

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Incidence rates of prostate cancer increase more sharply with age than for any other cancer [1]. Sixty percent of all newly diagnosed prostate cancer cases and almost 80% of all deaths occur in men aged 70 yr or older [3,4]. Prostate cancer mortality has been steadily declining over the past two decades [1]. However, the decline in mortality rate among African American men lags that among White men [1]. African American men have higher mortality, present late stage of cancer at diagnosis, and have lower mean age at death than White men [1,14–19]. Race and comorbidity are shown to be independent predictors of mortality for localized prostate cancer patients in addition to age, Gleason score and clinical stage of cancer [17,18,20,21]. There exists an ongoing debate regarding racial/ethnic variation in treatment modalities and cost of care for prostate cancer. The relationship between patient characteristic, health insurance status, provider characteristics (physician and hospital) and geographic characteristics is complex and must be taken into consideration while assessing the association between race/ethnicity and medical care cost for prostate cancer patients. This study aims to analyze [1] the incremental cost of prostate cancer, and [2] association of race with of direct medical care cost of prostate cancer. We hypothesized that racial variation exists in the direct medical care cost for prostate cancer care in a large urban academic hospital setting.

2. Materials and methods

A retrospective cohort control study design was used to collect clinical and cost data on a randomly selected group of 60 African American and 60 Non-Hispanic White prostate cancer patients treated at a large urban academic medical center. The two groups were matched by age and residential zip code. To be eligible for inclusion in the study, a patient had to be treated for prostate cancer between 1998 through 2001, with a minimum of 2 yr of enrollment in the health system; had to be at least 40-yr-old, and had to be of either African American or Non-Hispanic White race. Patients were excluded if they had un-staged prostate cancer, or visited the urology clinics to obtain a second opinion only and not to receive treatment. The control group consisted of 240 people without any cancer, matched by age, race, health insurance and residential zip code, selected from the same health care system database. Thus, this control group offered the appropriate baseline levels of healthcare/health status costs unrelated to cancer and enabled us to deal with the joint product issue that often afflicts cost of illness studies.

2.1. Data description

Detailed data on health resource utilization, types of procedures performed, and direct medical care charges were obtained from the Pennsylvania Integrated Clinical and Research Database (PICARD). This database integrates administrative, inpatient and outpatient information from the university practices, and data from other clinical networks. Sixty-seven percent of the population in this database was White and 20% was African American. Thus, the database reflected the area demographics served by this health system. The data used for measuring direct medical care costs of prostate cancer illness were: hospital care costs, physician and other professional caregivers payments, medication, costs related to detection, costs associated with initial and follow-up treatments, and treatment of complications. Medical care costs are defined as charges for specific services by any part of the health care organization. Costs per service were attributed to each service for every diagnosis for each study patient from actual charges for that patient. We used cost-to-charge ratio of 0.80 to compute actual medical center costs. Data on type and number of services received by a patient, including those attributable to prostate cancer, were obtained using Current Procedural Terminology (CPT) codes. Mean direct medical care cost per patient during the 12 months period was compared between racial groups. Two cost estimates of prostate cancer were developed and compared by race. First, mean costs of medical care attributable to prostate cancer were identified for specific services related to prostate cancer and compared between two racial groups [22]. Next, mean incremental direct medical care cost for patients with prostate cancer was compared between two racial groups. The difference in mean direct medical cost of care between the prostate and nonprostate groups was the incremental cost (marginal cost) that could be attributed to prostrate cancer treatment specifically.

Demographic characteristics (age, race, type of insurance, living arrangement, marital status and mortality) and clinical data [Prostate Specific Antigen (PSA) level, Gleason score, Charlson comorbidity score, TNM stage of cancer, and type of treatment] were obtained from the

Table 1
Characteristics of prostate cancer patients and controls across ethnicity

Prostate cancer patients	African American (n = 60)	White (n = 60)	P value
Mean age (years)	72.63 (SD = 11.9)	69 (9.5)	0.07
Charlson comorbidity score	4.5 (SD = 3.35)	2 (SD = 2.4)	<0.0001
Marital status			0.0572
Married	37 (62.7%)	47 (81.03%)	
Single	10 (16.9%)	8 (13.80%)	
Widowed	8 (13.6%)	1 (1.70%)	
Divorced	4 (6.8%)	2 (3.50%)	
Health insurance			0.224
Medicare	7 (11.7%)	6 (10.2%)	
Managed care	13 (21.7%)	23 (38.9%)	
Medicare-HMO	38 (63.3%)	29 (49.2%)	
Other	2 (3.3%)	1 (1.7%)	

Table 2
Characteristics of controls across ethnicity

	African American (n = 120)	White (n = 120)	P value
Age	72.64 (12.27)	69.11 (9.83)	0.0855
Charlson comorbidity score	3.87	1.46	<0.0001
Health insurance			0.234
Medicare	14 (11.72%)	13 (11%)	
Managed care	26 (21.7%)	46 (38.3%)	
Medicare-HMO	76 (63.3%)	59 (50%)	
Other	4 (3%)	2 (2%)	

clinical records and surgical pathologic reports using a structured chart abstraction sheet. Prostate cancer treatments included (1) Radiation (external beam, interstitial, extended field); (2) Surgery (pelvic LN dissection, TURP, orchiectomy, and radical prostatectomy); (3) Hormonal therapy and (4) Watchful waiting. Comorbidity is an important confounder for health resource utilization patterns. We computed Charlson comorbidity score (CHS) annually for each study participant. The Charlson comorbidity index is a medical record-based system, designed to predict death in longitudinal studies, with an integer score representing increasing level of the burden of illness [23]. The Charlson comorbidity score has been used effectively in many longitudinal studies using administrative data [23–25].

2.2. Statistical analysis

Most cost data suffer from non-normal distribution and our data was not an exception to this (skewness statistic = 1.96). Log transformation of direct medical care cost data reduced the skewness, but did not make the distribution normal (skewness statistic = −0.60). Thus, in addition to parametric tests, we also used nonparametric tests. For both groups (prostate cancer and control), we used bootstrap and t-test on log transformed data for comparing the mean direct medical care cost by race. Wilcoxon rank sum test was used to compare median direct medical care cost by race. Chi-square, Fisher's exact and Student's t-tests were used to compare age, Gleason score, PSA and treatment pattern across race. We determined factors associated with prostate cancer group and analyzed the incremental cost of prostate cancer using General Linear Model (GLM) for the log transformed data and Weibull model [26,27]. For the prostate cancer group, in the models for predicting total cost, we used the following independent variables: age, race, Charlson comorbidity score, and stage of cancer at the time of diagnosis. For estimating incremental cost, we used the entire sample (prostate cancer cases and controls) with the following independent variables: age, race, Charlson comorbidity score and presence of prostate cancer (yes or no). Ordinary least Square (OLS) regression may not prove to be appropriate for cost data as they tend to be highly skewed and a few extreme observations can influence the results. We corrected this problem by log transformation of the cost data.

We also analyzed cost data by using the Weibull model. This model is based on assumptions that are also appropriate for non-normally distributed cost data. In situations where these assumptions hold, the Weibull model proves to be an efficient model for cost data analysis. We used GLM model (for log-transformed cost data) and Weibull model to analyze the association between race and direct medical care cost. The response on log scale was retransformed and smearing estimator was used to correct for the retransformation bias [28].

3. Results

3.1. Demographic characteristics

Demographic characteristics of the study population are presented in Table 1. Mean age of African American prostate cancer patients was 72.6 yr, and that of White prostate cancer patients was 69 yr. African American prostate cancer patients had higher Charlson comorbidity scores compared to Whites, indicating higher prevalence of co-existing morbidity. The mean Charlson comorbidity score was different between African Americans and

Table 3
Disease characteristics and variations in treatment across ethnicity

Characteristics	African American (n = 60)	White (n = 60)	P value
PSA score (at the time of diagnosis)	19.4 (SD = 28.5)	13.4 (SD = 20.1)	0.197
PSA score (after treatment)	3.10 (SD = 10.3)	.94 (SD = 1.6)	0.167
Mean Gleason score	6.71 (SD = 1.66)	6.49 (SD = 1.21)	0.44
Lymph node involved-yes	5 (12.2%)	2 (4.3%)	0.169
TNM Stage			
T1c	0 (0.0%)	5 (10.2%)	0.0640
T2a T2b	32 (62.75%)	27 (55.10%)	
T3a T3b T3c T4a	19 (37.25%)	17 (34.69%)	
Positive for bone metastasis	5 (10.2%)	2 (4.4%)	0.1164

Table 4
Variations in treatments received by prostate cancer patients across ethnicity

Treatment type	African American (n = 60)	White (n = 60)	P
Radiation	33 (57%)	24 (42.1%)	0.113
Surgery	30 (52%)	40 (70%)	0.054
Hormone therapy	27 (47.4%)	21 (36.8%)	0.255
Watchful waiting	3 (5.08%)	2 (3.39%)	0.318
Radiation	7 (11.67%)	3 (5.08%)	0.118
Surgery + radiation	7 (11.67%)	5 (8.47%)	0.204
Radiation + hormone therapy	13 (21.67%)	11 (18.67%)	0.166
Surgery	14 (23.33%)	27 (45.76%)	0.010
Surgery + hormone therapy	3 (5.0%)	3 (5.0%)	0.320
Surgery + radiation + hormone	6 (10.0%)	5 (8.5%)	0.238
Hormone	5 (8.33%)	2 (3.4%)	0.167

Whites (4.5 vs. 2.0, $P \leq 0.0001$). Charlson comorbidity score increased with age for both racial groups. Health insurance status was comparable across race. For the control group (Table 2), the mean age of African Americans and Whites was not different (72.6 vs. 69.1, $P = 0.0855$). The Charlson comorbidity score was different between African Americans) and Whites (3.87 vs. 1.46, $P \leq 0.0001$). As with the prostate cancer group, the health insurance status of controls was comparable across race. These results indicated that cases and controls were well matched.

Table 3 shows clinical characteristics and type of treatment received by the prostate cancer group at the time of diagnosis. The PSA level was higher among African Americans than Whites, though the difference was not statistically significant. Gleason scores were comparable between racial and age groups and indicated that the tumor grades were moderately differentiated with a score 6.7 for African Americans and 6.5 for Whites. There was no difference in TNM stage of cancer at the time of diagnosis between the two racial groups. Proportion of patients with lymph node involvement and bone metastesis was similar across racial groups.

As seen from Table 4, a higher proportion of African Americans received radiation treatment, whereas a higher proportion of Whites received surgery. For both racial groups, a higher percent of elderly prostate cancer patients (≥65 yr) received radiation and hormone therapy. On the other hand, a higher percentage of younger patients (<65 yr) received surgery (results not reported). There was no racial difference among proportion of patients having hormone therapy, though older patients mostly received hormone therapy. Compared to African Americans, a higher proportion of Whites received surgery alone.

Table 5 presents comparisons by race using parametric and nonparametric tests of mean and median direct medical care cost for prostate cancer and control groups. Costs were not different across race for prostate cancer group using all three methods. However, controls showed significantly higher cost for African Americans than Whites.

Fig. 1 shows the relationship between total direct medical care cost and Charlson comorbidity score for both groups. For controls, we found an increasing trend between direct medical care cost and Charlson comorbidity score, leading to an inverse relationship between incremental cost of prostate cancer and Charlson comorbidity score. The highest incremental cost of $10,000 was observed between prostate cancer and control group when the Charlson comorbidity score was 0. This cost difference was reduced to $1000 as Charlson comorbidity score increased to between 1 and 3, and remained constant thereafter. This suggests that prostate cancer patients with no

Table 5
Cost of prostate cancer patients across ethnic groups

Cost	African American (n = 60)	White (n = 60)	P value
Total cost for PC			
Mean	15,749	16,674	log t-test = 0.54
Median	10,579	11,926	Wilcoxon rank sum test = 0.52
SD	18,126	16,601	Bootstrap = 0.37
Total cost of controls			
Mean	14,605	11,397	log t-test = 0.005
Median	10,133	4,860	Wilcoxon rank sum test = 0.014
SD	13,802	14,183	Bootstrap = 0.897
Incremental cost			
Mean	1,144	5,277	log t-test = 0.326
Median	675	4,891	Wilcoxon rank sum test = 0.12
SD	21,916	20,473	Bootstrap = 0.85
Prostate cancer cost (using CPT codes)			
Mean	4,021	5,739	log t-test = 0.089
Median	1,101	3,924	Wilcoxon rank sum test = 0.05
SD	5,526	6,894	Bootstrap = 0.65

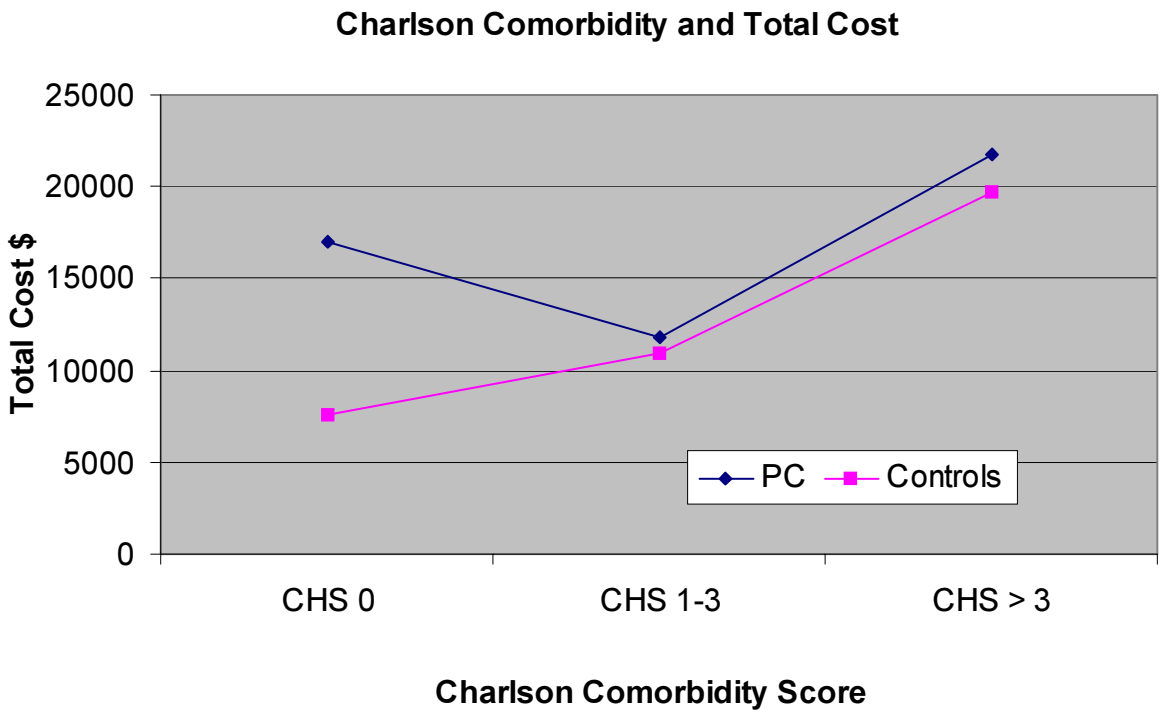

Fig. 1. Direct medical care cost and Charlson comorbidity. (Color version of figure is available online.)

comorbidity received the most intensive treatment leading to higher incremental cost. As comorbidity increased, prostate cancer patients might not have received aggressive treatment, as treating other chronic diseases then receives priority over a slow progressive disease such as prostate cancer.

Results of GLM with log-transformation (PROC GLM) and Weibull model (PROC LIFERG) to predict the incremental cost of prostate cancer were comparable and are presented in Table 6. Results from log-linear GLM model indicate that prostate cancer patients had 1.49 times higher total direct medical care cost compared to cancer-free controls. The Weibull model estimated incremental cost of prostate cancer to be 1.30 times the direct medical care cost of controls. The standard error for the Weibull model was comparable and smaller than the GLM model, indicating a better fit to the data. Both models were consistent in indicating that Charlson comorbidity score and presence of prostate cancer were statistically significant predictors of cost. Additionally, age was a significant predictor of direct medical care cost in the Weibull model.

We analyzed the effects of race as a predictor of total direct medical care cost for the prostate cancer group. The results of all both models yielded comparable results (Table 7). The statistic of interest is the coefficient of race after controlling for age, Charlson comorbidity score and TNM stage of cancer at the time of diagnosis. Race showed no effect on total direct medical care cost for prostate cancer patients, after controlling for these covariates. Also, in a secondary analysis (results not reported), we found that treatment modality was mostly influenced by comorbidity and age, rather than race.

4. Discussion

We observed some differences in treatment pattern by race. White prostate cancer group had lower comorbidity at diagnosis and a higher percent of them received surgery. Comorbidity, but not race, was a predictor of aggressive treatment. Earlier research has indicated that treatment pat-

Table 6
Incremental cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	*P* value	PE	SE	*P* value
Intercept	2208	0.55	<0.0001	3288	0.47	<0.0001
Age	1.008	0.008	0.279	1.016	0.006	0.013
Ethnicity (1 = AA)	1.04	0.194	0.82	0.96	0.159	0.83
Charlson comorbidity	1.66	0.232	0.029	1.29	0.192	0.049
Prostate cancer (1 = yes)	1.49	0.232	0.016	1.30	0.138	0.05

Table 7
Direct medical care cost of patients with prostate cancer

Independent variables	Log model			Weibull model		
	PE	SE	*P* value	PE	SE	
Intercept	6836	0.21	<0.0001	14617	0.17	<0.0001
Age (≥65 yr = 1)	1.30	0.22	0.24	0.98	0.19	0.94
Ethnicity (1 = AA)	0.69	0.22	0.1044	0.70	0.19	0.07
Charlson comorbidity	1.11	0.036	0.0036	1.09	0.031	0.005
Stage (early stage = 1)	1.17	0.22	0.459	0.95	0.19	0.81

terns differ across racial/ethnic groups [19,29–34]. African Americans were less likely to receive aggressive therapy than Whites [29,31]. For localized and regional disease stages, White men were more likely than African Americans to receive radical prostatectomy, while African Americans were more likely to receive radiation therapy [29–31]. However, recent studies have shown a decreasing trend in racial/ethnic disparities in treatment modalities for the prostate cancer and, in an academic hospital, race was shown to be a conditional predictor of outcome [33,34]. Age, too, strongly influenced treatment pattern, with younger men tending to have radical prostatectomy, middle aged men tending to have radiation therapy and older men tending to have either no treatment or hormone therapy [20,30]. Our results regarding age and treatment pattern appeared to be supportive of these earlier findings.

Initial cost of prostate cancer decreases with age and more than 50% of treatment costs of prostate cancer were accrued during the patient's last year of life [12]. Other studies have reported significant differences in cost across type of treatment [10,35,37,39–48]. Wide ranges of cost estimates associated with prostate cancer across different stages of cancer were derived using prospective and retrospective study design [6,9,11,35–49]. In addition, earlier research indicated that cost of care for prostate cancer varied significantly by race [22]. However, in this study, clinical data on TNM stage, Gleason and PSA scores at the time of diagnosis was not used. No adjustment was made for provider characteristics (type of hospital and physician); the issue of joint product in the analysis of cost data was not addressed. Finally, non-normal distribution of cost data was not rectified. In this study, after controlling for age, stage of cancer at the time of diagnosis, hospital characteristics and stage of cancer, we found no association between race and direct medical care cost of prostate cancer. The incremental cost of prostate cancer was 1.3 times higher than comparable controls.

5. Conclusions

Incremental cost analysis is an integral part of health outcome research. The economic burden of prostate cancer, more clearly defined by incremental cost analysis in control studies, is significant. Patients with prostate cancer had at least 1.3 times higher total annual direct medical cost compared to noncancer patients, after controlling for age and Charlson comorbidity score. African American patients with prostate cancer presented with higher comorbidity and higher PSA level, with these two variables influencing direct medical care cost. Also, age influenced treatment patterns, which in turn influenced direct medical care cost. Thus, we conclude that total direct medical care cost of prostate cancer treatment offered in a large urban academic hospital setting was not associated with race after controlling for age, Charlson comorbidity score and PSA level at the time of diagnosis. As comorbidity increases, the chances of receiving aggressive treatment for prostate cancer decrease, thus leading to a reduction in incremental cost. Also, as age at diagnosis increases, so does the probability of dying from causes other than prostate cancer, especially for patients with lower-grade or earlier-stage disease.

Further work is needed to validate our results, with a comprehensive study using a large national database. Such a study would be able to address the issues of bias because of geographical variations in treatment patterns, bias because of socioeconomic status, insurance status, and because of provider characteristics (physician, hospital).

5.1. Study limitations

Study limitations are: (1) potential bias for inconsistency in the reported (PICARD) and actual services provided; (2) unknown external validity given that the study population is from a single university medical center, albeit one with large group of prostate cancer patients. However, the percent of African Americans patients in the Urology department at this medical center mirrors that of the 8-county region from which the large majority of all medical center patients are drawn; (3) indirect cost of prostate cancer (associated with caregivers, loss of productivity, early morality, etc.) are not considered in our analysis that could considerably affect total cost.

Acknowledgments

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Health Related Quality of Life and Direct Medical Care Cost of Prostate Cancer Patients

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Abstract

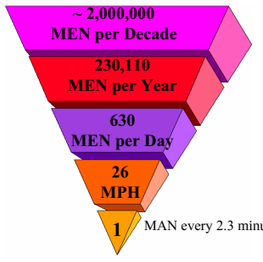
(a) Introduction and Objective: Multiple factors (demographic, clinical, social, economic and environmental) influence the medical care cost and health related quality of life (HRQoL) of patients with prostate cancer (PCa). It is important to assess the factors associated with variations in health resource utilization, costs and their relationship to outcomes for effective management and policy decision. We evaluated generic and prostate-specific HRQoL and direct medical care cost of men with PCa.

(b) Methods and Statistical Analysis: We conducted a prospective cohort study of newly diagnosed PCa patients, recruited from the Urology clinics of a large academic health care system and VA hospital. Additionally, we recruited matched controls (cancer free) from same hospitals. All PCa participants completed SF-36 and UCLA-PCI surveys prior to treatment, and at 3,6,12 and 24 months follow-ups. Controls completed surveys at baseline only. Direct medical care cost (DMC) data were obtained from a hospital based administrative database and clinical data were obtained via structured medical chart review. Demographics and HRQoL were compared using T-test, Fisher Exact and Chi-square. Wilcoxon and long-t Tests were used to compare DMC. Multivariate regression models were used to assess incremental cost of PCa and the predictors of 24 months PCa specific HRQoL.

(c) Results: We recruited 368 PCa patients and achieved a retention rate of 85%. PCa patients showed significant variations in baseline characteristics, treatment pattern and HRQoL by hospitals, age and ethnicity. For PCa patients who had 24 months follow-up, mean annual medical care cost was $4,160 for treatment year and mean length of stay was 3.5days. Baseline physical function for cases was nine points higher than controls (72.6 vs. 61: p=.011) and score on bodily pain was higher, indicating lower pain (91.5 vs. 76.9 p=.0054). For baseline prostate specific HRQoL (UCLA-PCI), cases had better functions on sexual function (71.5 vs 48.7 p=.0009), bowel bother (96.9 vs 86 p=.0160) and sexual bother (89.1 vs 69.4 p=.016). At 12 months post treatment, cases had generic HRQoL similar to their baseline values and those of controls for all domains. Urinary function (80.1 vs. 93.9: p=.0019), sexual function (39.4 vs. 71.5: p<.0001), urinary bother (83.1 vs. 94.1: p=.032) and sexual bother (35.5 vs. 89.1: p<.0001) were lower at 12 months for cases than baseline values, while rest of the PCI domains were comparable. At 24 months of post treatment, generic HRQoL of cases returned to their baseline values. Urinary function (77.2 vs. 93.9: p=.0014), sexual function (42.7 vs. 71.5: p=<.0001), and sexual bother (41.1 vs. 89.1: p<.0001) were lower and rest of the PCI domains were comparable. In a multivariate log-linear regression, marital status was a significant predictor of sexual, urinary and bowel functions at 24 months.

(d) Conclusions: PCa patients reported weaker sexual function, urinary function and sexual bother at 24 months post treatment compared to their baseline values. Baseline characteristics, treatment pattern and HRQoL vary across age, ethnicity and hospital settings. Thus, there exists a significant opportunity for improving prostate specific HRQoL of men with PCa.

Estimated New Prostate Cancer Patients



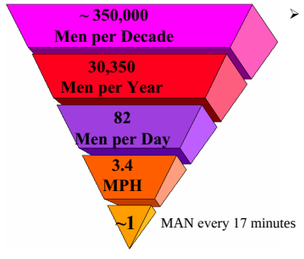
Probability of developing prostate cancer-

1 in 39 (age 40 to 59 yrs)

1 in 7 (age 60 to 79 yrs)

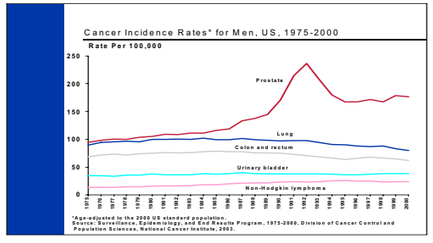
African American men (274 per 100,000) are 1.6 times more likely to be diagnosed with Pca than White men. (171 per 100,000)

Prostate Cancer Mortality



- Although the mortality rates are declining, the rates are still disproportionately higher in African-American men.

Cancer Incidence Rates



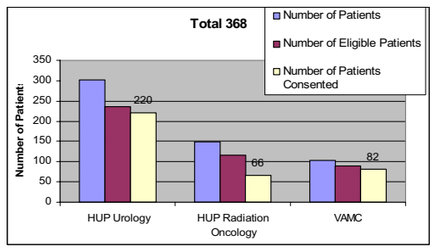
Objectives

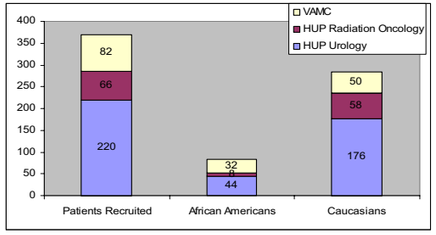
- To analyze and compare quality of life and satisfaction with care for prostate cancer across Caucasian and African American men, controlling for disease stage at diagnosis and comorbidity.
- To analyze and compare average cost of care for prostate cancer patients across two ethnic groups, controlling for disease stage at diagnosis and comorbidity.
- To analyze and compare the resource utilization and treatment modalities and cost-effectiveness of prostate cancer treatment between VA and non-VA hospitals.

Methods

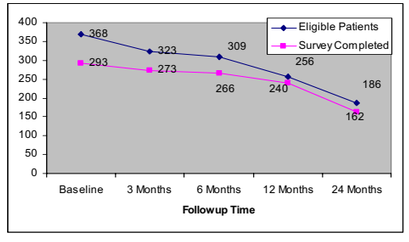
- **Prospective Cohort Design**
- **Study participants:** African American or Caucasian men diagnosed for prostate cancer were recruited (n=368) within four months of their diagnosis and prior to treatment from: HUP Urology Clinic, Radiation Oncology and VAMC.
- HRQoL and satisfaction with care data (at baseline, 3 6, 12 and 24 months) was obtained using UCLA Prostate Cancer Index (PCI) and SF-36. Quality of Well-Being-QWB-SA.
- Health resource utilization and direct medical care cost ⇒ PICARD and for VA patients through unit cost approach.
- Clinical data ⇒ Medical Chart review

Recruitment





Patient Follow-up & Retention



Results

Predictors of 24 months HRQoL:

- Marital status and Charlson comorbidity score were significant predictors of 24-month scores on social function, bodily pain and general health.
- In a multivariate regression, marital status was a significant predictor of five domains of prostate-specific HRQoL at 24 months.
- Those receiving radical prostatectomy alone (vs. adjuvant therapy) had better score on 24-month bodily pain, indicating lower pain.
- Higher TNM stage was associated with poorer general health at 24 months.

Table 1: Baseline Demographic characteristics, signs and symptoms

Covariates	Prostate cancer cases	Controls	p value
Age (in years)	57.7 (sd=5.2)	59.3 (sd=3.4)	.1347
Charlson comorbidity	1.76 (sd=2.9)	0.79 (1.6)	.0956
Race (Caucasian %)	77	77	.9704
Signs and symptoms (%)			
Difficulty or discomfort urinating	26.5	6	.044
Having to urinate too often	27.3	20.6	.57
Weak urinary stream	29.4	5.9	.023
Infection of bladder or prostate	3	2.94	.51
Blood in urine	0	2.94	.5
Pain or aches in back, hips or legs	11.76	50	.0003
More tired or worn out than usual	18.2	20.6	.23

Table 2: Clinical characteristics of prostate cancer patients

Characteristics	African American (n=60)	Caucasians (n=60)	p value
PSA score (at the time of diagnosis)	19.4 (sd=28.5)	13.4 (sd=20.1)	0.197
PSA score (after treatment)	3.10 (sd=10.3)	.94 (sd=1.6)	0.167
Mean Gleason score	6.71 (sd=1.66)	6.49 (sd=1.21)	0.44
Lymph node involved-yes	5 (12.2%)	2 (4.3%)	0.169
TNM Stage T1c T2a T2b T3a T3b T3c T4a	 0 (0.0%) 32 (62.75%) 19 (37.25%)	 5 (10.2%) 27 (55.10%) 17 (34.69%)	.0640
Positive for bone metastasis	5 (10.2%)	2 (4.4%)	.1164

Type of Treatment Received by Ethnicity

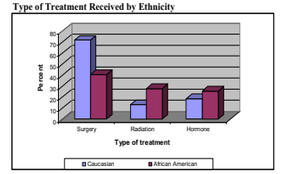


Table 3: Comparison of average total cost of prostate cancer

Cost	African American (n=60)	Caucasians (n=60)	p value
Total cost for PC Mean Median Standard Deviation	 15,749 10,579 18,126	 16,674 11,926 16,601	log-heal = .24 Wilcoxon Rank-Sum test = .32 Bootstrap p = .37
Total cost of controls Mean Median Standard Deviation	 14,605 10,133 13,802	 11,397 4,860 14,183	log-heal = .005 Wilcoxon Rank-Sum test = .01 Bootstrap p = .007
Incremental cost Mean Median Standard Deviation	 1,144 675 21,916	 5,277 4,891 20,473	log-heal = .226 Wilcoxon Rank-Sum test = .12 Bootstrap p = .85
Prostate cancer cost (using CPT codes) Mean Median Standard Deviation	 4,021 1,101 5,526	 5,739 3,924 6,894	log-heal = .009 Wilcoxon Rank-Sum test = .05 Bootstrap p = .67

Figure 1: Progression of Generic Quality of Life

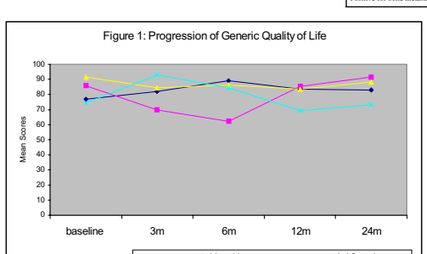


Figure 2: Progression of Generic Quality of Life

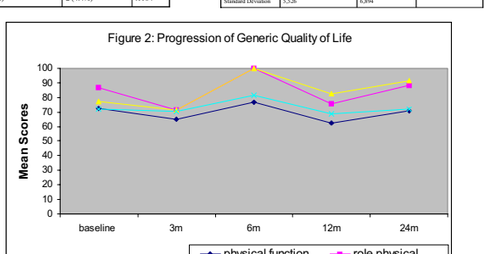


Figure 3: Progression of HRQoL

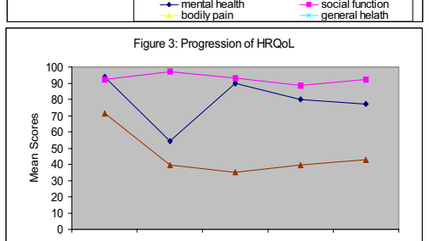
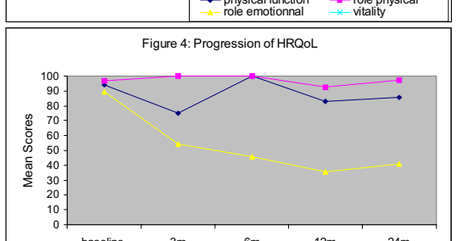


Figure 4: Progression of HRQoL



Conclusions

- Baseline characteristics, treatment pattern and HRQoL vary across age, ethnicity and hospital settings.
- Mean cost of prostate cancer treatment for African American group was $5,027 and for Caucasian group was $7,174.
- Mean cost of prostate cancer treatment was 15% lower for the age group ? 65 years, than for age group < 65 years.
- Charlson comorbidity, age and ethnicity are important factors associated with the cost of care and type of treatment received by prostate cancer patients.
- Prostate cancer patients reported weaker sexual function, urinary function and sexual bother at two years post treatment compared to their baseline values.
- There exists an opportunity for improving prostate specific HRQoL of men with early stage of prostate cancer.

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